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Aluminum Phosphide
Pesticide Registration Standard

(U.S.) Environmental Protection Agency
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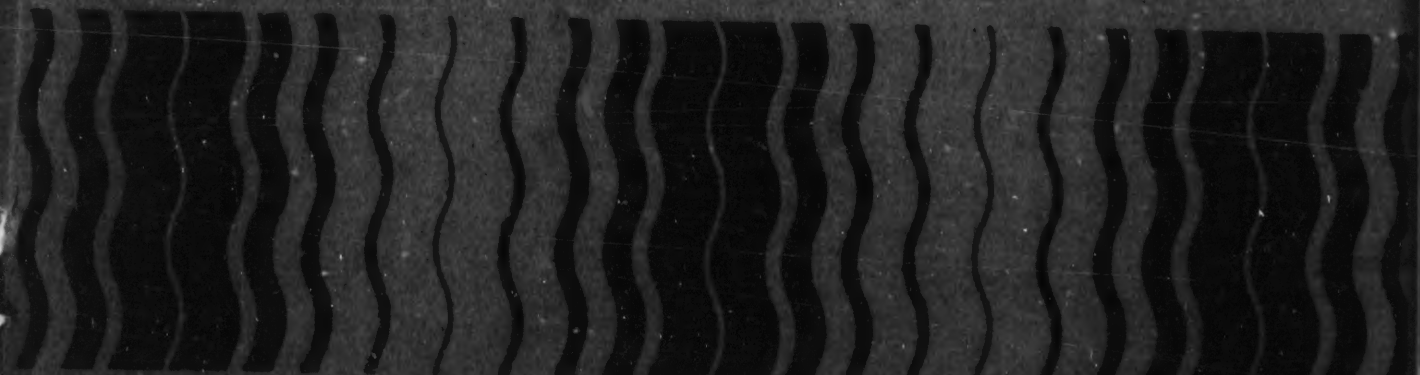
Aluminum Phosphide

Pesticide Registration Standard



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I. How to Register Under a Registration Standard

A. Organization of the Standard

The first part of this document explains the purpose of a Registration Standard and summarizes the legal principles involved in registering or reregistering under a Standard. The second part presents the Agency's regulatory position and rationale. The third part sets forth the requirements, in tabular form, that must be met to obtain or retain registration for products covered by this particular Registration Standard. In the remaining parts, the Agency reviews the available data by scientific discipline, discusses the Agency's concerns with the identified potential hazards, and logically develops the conditions and requirements that would reduce those hazards to acceptable levels.

B. Purpose of the Standard

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides that "no person in any State may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver to any person any pesticide which is not registered with the Administrator [of EPA]." To approve the registration of a pesticide, the Administrator must find, pursuant to Section 3(c)(5) that:

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

In making these findings, the Agency reviews a wide range of data which registrants are required to submit, and assesses the risks associated with the use of the proposed pesticide. However, the established approach to making these findings has been found to be defective on two counts.

First, the Environmental Protection Agency (EPA) and its predecessor agency, the United States Department of Agriculture (USDA), routinely reviewed registration applications on a "product-by-product" basis, evaluating each product-specific application somewhat independently. In the review of products containing similar components, there was little opportunity for a retrospective review of the full range of pertinent data available in Agency files and in the public literature. Thus the "product-by-product" approach was often inefficient and sometimes resulted in inconsistent or incomplete regulatory judgments.

Second, over the years, as a result of inevitable and continuing advances in scientific knowledge, methodology, and policy, the data base for many pesticides came to be considered inadequate by current scientific and regulatory standards. Given the long history of pesticide regulation in several agencies, it is even possible that materials may have been lost from the data files.

When EPA issued new requirements for registration in 1975 (40 CFR 162) and proposed new guidelines for hazard testing in 1978 (43 FR 29686, July 10, 1978 and 43 FR 37336, August 22, 1978) and in 1980 (45 FR 72948, November 3, 1980), many products that had already been registered for years were being sold and used without the same assurances of human and environmental safety as was being required for new products. Because of this inconsistency, Congress directed EPA to reregister all previously registered products, so as to bring their registrations and their data bases into compliance with current requirements [see FIFRA Section 3(g)].

Facing the enormous job of re-reviewing and calling-in new data for the approximately 35,000 current registrations, and realizing the inefficiencies of the "product-by-product" approach, the Agency decided that a new, more effective method of review was needed.

A new review procedure has been developed. Under it, EPA publishes documents called Registration Standards, each of which discusses a particular pesticide active ingredient. Each Registration Standard summarizes all the data available to the Agency on a particular active ingredient and its current uses, and sets forth the Agency's comprehensive position on the conditions and requirements for registration of all existing and future products which contain that active ingredient. These conditions and requirements, all of which must be met to obtain or retain full registration or reregistration under Section 3(c)(5) of FIFRA, include the submission of needed scientific data which the Agency does not now have; compliance with standards of toxicity, composition, labeling, and packaging; and satisfaction of the compensation provisions of FIFRA Section 3(c)(1)(D).

The Standard will also serve as a tool for product classification. As part of the registration of a pesticide product, EPA may classify each product for "general use" or "restricted use" [FIFRA Section 3(d)]. A pesticide is classified for "restricted use" when some special regulatory restriction is needed to ensure against unreasonable adverse effects to man or the environment. Many such risks of unreasonable adverse effects can be lessened if expressly designed label precautions are strictly followed. Thus, the special regulatory restriction for a "restricted use" pesticide is usually a requirement that it be applied only by, or under the supervision of, an applicator who has been certified by the State or Federal government as being competent to use pesticides safely, responsibly, and in accordance with label directions. A restricted use pesticide can have other regulatory restrictions [40 CFR 162.11(c)(5)] instead of, or in addition to, the certified applicator requirement. These other regulatory restrictions may include such actions as seasonal or regional limitations on use, or a requirement for the monitoring of residue levels after use. A pesticide classified for "general use", or not classified at all, is available for use by any individual who is in compliance with State and local regulations. The Registration Standard review compares information about potential adverse effects of specific uses of the pesticide with risk criteria listed in 40 CFR 162.11(c), and thereby determines whether a product needs to be classified for "restricted use." If the Standard does classify a pesticide for "restricted use," this determination is stated in Part II of this Standard.

C. Requirement to Reregister Under the Standard

FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all currently registered products as expeditiously as possible. Congress also agreed that reregistration should be accomplished by the use of Registration Standards.

Each registrant of a currently registered product to which this Standard applies, and who wishes to continue to sell or distribute such product in commerce, must apply for reregistration. This application must contain proposed labeling that complies with this Standard.

EPA will issue a notice of intent to cancel the registration of any currently registered product to which this Standard applies, if the registrant fails to comply with the procedures for reregistration set forth in the Guidance Package which accompanies this Standard.

D. "Product-Specific" Data and "Generic" Data

In the course of developing this Standard, EPA has determined the types of data needed for evaluation of the properties and effects of products to which the Standard applies, in the disciplinary areas of Product Chemistry, Environmental Fate, Toxicology, Ecological Effects and Residue Chemistry. These determinations are based primarily on the data Guidelines proposed in 1978 (43 FR 29686, July 10, 1978, and 43 FR 37336, August 22, 1978), and in 1980 (45 FR 72948, November 3, 1980), as applied to the use patterns of the products to which this Standard applies. Where it appeared that data from a normally applicable Guidelines requirement were actually unnecessary to evaluate these products, the Standard indicates that the requirement has been waived. On the other hand, in some cases studies not required by the Guidelines may be needed because of the particular composition or use pattern of products the Standard covers; if so, the Standard explains the Agency's reasoning. Data guidelines have not yet been proposed for the Residue Chemistry discipline, but the requirements for such data have been in effect for some time and are, the Agency believes, relatively familiar to registrants. Data which the Agency has found are needed to evaluate the registrability of some products covered by the Standard may not be needed for the evaulation of other products, depending upon the composition, formulation type, and intended use of the product in question. The Standard states which data requirements apply to which product use categories (see Part III).

The various kinds of data normally required for registration of a pesticide product can be divided into two basic groups:

1) data that are "product-specific," i.e., data that relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition); and

2) "generic" data that pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use.

The Agency requires certain "product-specific" data for each product to characterize the product's particular composition and physical/chemical properties (Product Chemistry), and to characterize the product's acute toxicity (which is a function of its total composition). The applicant for registration or reregistration of any product, whether it is a manufacturing-use or end-use product, and without regard to its intended use pattern, must submit or cite enough of this kind of data to allow EPA to evaluate the product. For such purposes, "product-specific" data on any product other than the applicant's are irrelevant, unless the other product is similar in composition to the applicant's. (Where it has been found practical to group similar products for purposes of evaluating, the Standard indicates guideline requirements that support similar products.) "Product-specific" data on the efficacy of particular end-use products are also required where the formulation may affect public health or where failure of efficacy could cause public health problems (see 44 FR 27932, May 11, 1979).

All other data needed to evaluate pesticide products concern the properties or effects of a particular ingredient (normally a pesticidally active ingredient, but in some cases a pesticidally inactive or "inert" ingredient). Some data in this "generic" category are required to evaluate the properties and effects of all products containing that ingredient, e.g., the acute LD_{50} of the active ingredient in the technical or purest grade (see proposed 40 CFR 163.81-1(a), 43 FR 37355).

Other "generic" data are required to evaluate all products which both contain a particular ingredient and are intended for certain uses (see proposed 40 CFR 163.82-1, 43 FR 37363, which requires subchronic oral testing of the active ingredient with respect to certain use patterns only). Where a particular data requirement is use pattern dependent, it will apply to each end-use product which is to be labeled for that use pattern (except where such end-use product is formulated from a registered manufacturing-use product permitting such formulations) and to each manufacturing-use product with labeling that allows it to be used to make end-use products with that use pattern. Thus, for example, a subchronic oral dosing study is needed to evaluate the safety of any manufacturing-use product that legally would be used to make an end-use, food crop pesticide. However, if an end-use product's label specified that it was for use only in ways that did not involve a food/feed exposure or repeated human exposure via the oral route, then the subchronic oral study would not be relevant to the evaluation of the manufacturing-use product.

If a registrant of a currently registered end-use product wishes to avoid the costs of data compensation under FIFRA Section 3(c)(1)(D) or data generation under Section 3(c)(2)(B) for "generic" data that are required only with respect to some use patterns, he may elect to delete those use patterns from his labeling at the time he reregisters his products. An applicant for registration of a new product under this Standard may similarly request approval for only certain use patterns.

E. Data Compensation Requirements Under FIFRA 3(c)(1)(D)

Under FIFRA Section 3(c)(1)(D), an applicant for registration, reregistration or amended registration must offer to pay compensation for certain existing data the Agency has used in developing the Registration Standard. Compensation must be offered for all data which are described by all the following criteria:

1) the data were first submitted to EPA or to its predecessor agency, USDA, or FDA on or after January 1, 1970;

2) the data were submitted to EPA (or USDA or FDA) by some other applicant or registrant in support of an application for an experimental use permit or a

tolerance, an amendment adding a new use to a registration, or for reregistration, or to support or maintain in effect an existing registration;

3) the data are relevant to the Agency's decision to register or reregister the applicant's product under the Registration Standard, taking into account the applicant's product composition and intended use pattern(s);

4) the data are determined by EPA to be valid and usable in reaching regulatory conclusions; and

5) the data are not those for which the applicant has been exempted by FIFRA Section 3(a)(2)(D) from the study to offer to pay compensation. (This exemption applies to the "generic" product, not to "product-specific" data. The exemption is available only to an applicant whose end-use product is formulated from another registered manufacturing-use product containing that active ingredient.)

An applicant for reregistration of an already registered product under this Standard, or for registration of a new product under this Standard, accordingly must determine which of the data used by EPA in developing the Standard must be the subject of an offer to pay compensation, and must submit with his application the appropriate statements evidencing his compliance with FIFRA Section 3(c)(1)(D). An applicant would never be required to offer to pay for "product-specific" data submitted by another firm. In many, if not in most cases, data which are specific to another firm's product will not suffice to allow EPA to evaluate the applicant's product; that is, will not be useful to the Agency in determining whether the applicant's product is registrable. There may be cases, however, where, because of close similarities between the composition of two or more products, another firm's data may suffice to allow EPA to evaluate some or all of the "product-specific" aspects of the applicant's product. In such a case, the applicant may choose to cite that data instead of submitting data from tests on his own product, and if he chooses that option, he would have to comply with the offer-to-pay requirements of Section 3(c)(1)(D) for that data.

Each applicant for registration or reregistration of a manufacturing-use product, and each applicant for registration or reregistration of an end-use product, who is not exempted by FIFRA Section 3(c)(2)(D), must comply with the Section 3(c)(1)(D) requirements. This is with respect to each item of "generic" data that relates to his product's intended uses.

A detailed description of the procedures an applicant must follow in applying for reregistration (or new registration) under this Standard is found in the Guidance Package for this Standard.

F. Obtaining Data to Fill Data Gaps; FIFRA 3(c)(2)(B)

Some of the kinds of data EPA needs for its evaluation of the properties and effects of products to which this Standard applies have not been submitted to the Agency (or, if submitted, have been found to have deficiencies rendering them inadequate for making registration oriented decisions) and have not been located in the published literature search that EPA conducted in preparation of this Standard. Such instances of missing but required data are referred to in this Standard as "data gaps."

FIFRA Section 3(c)(2)(B), added to FIFRA by the Congress in 1978, authorizes EPA to require registrants to whom a data requirement applies, to generate (or otherwise produce) data to fill such "gaps" and submit those data to EPA. EPA must allow a reasonably sufficient period for this to be accomplished. If a registrant fails to take appropriate and timely steps to fill the data gaps identified by a Section 3(c)(2)(B) order, his product registration may be suspended until the data are submitted. A mechanism is provided whereby two or more registrants may agree to share in the costs of producing data for which they are both responsible.

The Standard lists, in Part III, the "generic" data gaps and "product-specific" data gaps for end-use products. It also notes the classes of products to which these data gaps pertain. The Standard also points out that to be registered under the Standard, a product must be supported by certain required "product-specific" data on one currently registered product, but may lack such data on another. Only those Standards which apply to a very small number of currently registered products will attempt to state definitively the "product-specific" data gaps on a "product-by-product" basis. (The Standard will, in some cases, note which data EPA possesses that would suffice to satisfy certain "product-specific" data requirements for a category of products with similar composition characteristics.)

As part of the process of reregistering currently registered products, EPA will issue FIFRA Section 3(c)(2)(B) directives requiring the registrants to take appropriate steps to fill all identified data gaps, whether "product-specific" or "generic" data gaps. The Guidance Package for this Standard details the steps that must be taken by registrants to comply with Section 3(c)(2)(B).

In addition, FIFRA Section 6(a)(2) requires the registrant to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. The registrant should notify the Agency of interim results of studies in progress, if those results show possible adverse effects.

G. Amendments to the Standard

Applications for registration which propose uses or formulations that are not presently covered by the Standard, or which present product compositions, hazard data, toxicity levels, or labeling that do not meet the requirements of the Standard, will automatically be considered by the Agency to be requests for amendments to the Standard. In response to such applications, the Agency may request additional data to support the proposed amendment to the Standard, or may deny the application for registration on the grounds that the proposed product would cause unreasonable adverse effects to the environment. In the former case, when additional data have been satisfactorily supplied, and providing that the data do not indicate the potential for unreasonable adverse effects, the Agency will then amend the Standard to cover the new registration.

Each Registration Standard is based upon all data and information available to the Agency's reviewers on a particular date prior to the publication date. This "cut-off" date is stated at the beginning of the Part II.C. Any subsequent data submissions and any approved amendments will be incorporated into the Registration Standard by means of addenda, which are available for inspection at EPA in Washington, D.C., or copies may be requested from the Agency. When all of the present "data gaps" have been filled and the submitted data have been reviewed, the Agency will revise the Registration Standard. Thereafter, when the Agency determines that the internally maintained addenda have significantly altered the conditions for registration under the Standard, the document will be updated and reissued for publication.

While Registration Standard discusses only the uses and hazards of products containing the designated active ingredient(s), the Agency is also concerned with the potential hazards of some inert ingredients and impurities. Independent of the development of any one Standard, the Agency has initiated the evaluation of some inert pesticide ingredients. Where the Agency has identified inert ingredients of concern in a specific product to which the Standard applies, these ingredients will be indicated in the Guidance Package.

II. Regulatory Position

A. Introduction

This Part presents the Agency's regulatory position and rationale based on an evaluation of all registered products containing aluminum phosphide as the sole active ingredient with the same use patterns described in this Standard. After briefly describing the chemical, this Part presents the regulatory position and rationale, the criteria by which applications for registration of aluminum phosphide products will be approved, additional labeling considerations and requirements related to the tolerance reassessment, if applicable. A summary of the data requirements is contained in Part III. Discussion of the data upon which this regulatory position is based is presented in each of the disciplinary chapters, Parts IV through VIII.

B. Description of Chemical

Aluminum phosphide is a restricted use, nondomestic fumigant, for use only by certified applicators for the control of insects in raw agricultural commodities, processed foods and animal feeds, and other nonfood/nonfeed commodities (including tobacco). The Agency has also given preliminary acceptance for the control of burrowing rodents in noncrop areas. Although aluminum phosphide is the registered active ingredient for this pesticide, phosphine gas, which is liberated in the presence of moisture, actually performs the fumigant action for this pesticide. The American Chemical Society's Chemical Abstracts Service (CAS) number for aluminum phosphide is 20859-73-8 and the EPA Shaughnessy number is 066501. Currently, there are no technical or manufacturing-use products registered with the Agency. Aluminum phosphide end-use products imported into this country are produced in an intergrated-formulation system. That is, the technical material is formulated directly into an end-use product. Consequently, although the Agency has some information on the manufacturing process for end-use products, sufficient description of the manufacturing process for each technical grade of aluminum phosphide used to produce these end-use products is lacking.

C. Regulatory Position

Aluminum phosphide, as decribed in this Standard, may be registered for sale, distribution, and use in the United States. The Agency has considered the limited amount of scientific data concerning aluminum phosphide and phosphine obtained from the open literature as of October, 1981, and the data submitted to the Agency by the registrants through the time of publication of this Standard (October, 1981). Based on review of these limited data, the Agency finds that none of the risk criteria found in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations (CFR) were met or exceeded for aluminum phosphide and that it does not appear to cause unreasonable adverse effects when applied in accordance with proper label directions and precautions. Aluminum phosphide products currently registered may be reregistered subject to the conditions imposed for data requirements. New products may be registered under this Standard and are subject to the same requirements. Revised label requirements will be addressed in the Guidance Package which accompanies this Standard and any special label requirements for this pesticide will also be discribed in Part II.E of this Standard (see 40 CFR 162.10 for a detailed description of standard labeling requirements).

D. Regulatory Rationale

A review of the available data regarding the end-use products of aluminum phosphide and its principle active agent, phosphine, shows that much information that could be used to support registration and reregistration is not available. The Agency has the prerogative not only to request information to satisfy the data Guidelines proposed in 1978 and 1980, but may also require additional testing. These additional tests may be requested by the Agency if it believes that particular concerns regarding the health or environmental effects of a pesticide must be evaluated. In some cases, this additional testing may be deferred pending the Agency's review of specific test protocols developed by the registrant or the completion of other related tests the Agency requires for registration of a product (e.g., tiered testing).

It is the policy of the Agency not to automatically request guideline information just because a particular guideline exists. Each element of the guideline is considered individually with regard to the pesticide's uses, exposure and risk. If the Agency concludes that specific elements of the data guidelines are required to prepare a comprehensive Registration Standard, the data will be requested.

The Agency has concluded that it should continue registration for this product for the following reasons:

1) Because phosphine gas has a high acute inhalation toxicity, the insecticide uses of aluminum phosphide are restricted to certified applicators who are required to wear protective clothing and a respirator during the application process. Certified applicators will also be required to wear protective clothing (e.g., gloves) when applying the aluminum phosphide as a rodenticide. Consequently, the Agency does not believe the use of this pesticide presents any unreasonable acute risk when used in accordance with label instructions.

2) No significant chronic adverse effects have been uncovered in the review of studies pertinent to aluminum phosphide or phosphine. These studies include some which, while failing to meet guideline requirements, provide a level of qualitative information. As a result of examining these studies, the Agency has concluded that there is no immediate cause for regulatory concern based on chronic effects.

3) In accordance with FIFRA, the Agency does not routinely cancel the registration of products or withhold registration merely for the lack of data (see Sections 3(c)(2)(B) and 3(c)(7) of FIFRA). Rather, the publication of this Standard provides a mechanism for identifying data needs, and registration of aluminum phosphide under this Standard allows for the improvement of labels during the period in which the required data are being generated. When these data are received, they will be reviewed by the Agency and the registerability of the chemical will be reassessed.

4) If the label instructions are followed, applicators should not be exposed to measurable levels of the pesticide during the fumigation of commodities. However, reentry data are being required to evaluate more precisely the concentration levels of phosphine, if any, following the fumigation process.

5) The Agency is requiring label revisions for the rodenticide fumigant products which will eliminate potential hazards to nontarget organisms.

In addition, the Agency is waiving or reserving some data requirements for aluminum phosphide or phosphine for the following reasons:

1) The label requires the application site to be airtight and capable of containing the liberated phosphine gas. Consequently, there should be no exposure to the applicator or others who live or work in the immediate fumigation area. When aerating the application site after fumigation, the label also requires the applicator to wear protective equipment (e.g., respirator) when testing the site to certify that phosphine gas has been reduce to levels safe for reentry. The current reentry level, 0.3 ppm, is based on acute and subchronic inhalation studies for phosphine gas established through the Occupational Safety and Health Administration's (OSHA) Permissible Exposure Level (PEL). It is possible that this level may not protect the applicator from other chronic adverse effects. However, the post-fumigation atmosphere theoretically should decrease to some concentration approaching zero as the site is further aerated. Thus, the Agency will hold in abeyance further testing for teratology, mutagenicity, and subchronic inhalation until the Agency receives and reviews the requested environmental reentry data to determine the exposure, if any, to the applicator. If there is significant exposure to the applicator based on this review, the existing PEL may not be adequate to protect applicators reentering aluminum phosphide-treated storage areas from other chronic adverse effects and the Agency may require these studies.

2) Three types of tolerances have been established for aluminum phosphide for the amount of phosphine in or on commodities: 1) 0.1 ppm on raw agricultural commodities [seed and pod vegetables (except soybeans): 0.01 ppm] (40 CFR Section 180.255); 2) 0.01 ppm on processed foods (21 CFR Section 193.20); and 3) 0.1 ppm on animal feed (21 CFR Section 561.40). The tolerance of 0.1 ppm is being allowed for raw agricultural commodities since residual phosphine will probably dissipate from the commodity or will be converted to oxy-acids of phosphorus which the Agency has determined to be toxicologically insignificant. Any unreacted aluminum phosphide which might remain if the formulations are added to the commodity is expected to be converted to minute amounts of phosphine gas which is readily dissipated from the commodity upon further aeration. However, radiolabeled phosphorus studies (see Part VI, Residue Chemistry) indicate that a substantial portion (about 30%) of the phosphine conversion products have not been identified. Thus the Agency will hold in abeyance further testing for chronic feeding, oncogenicity, metabolism, and reproductive until these unidentified residues are identified. If the Agency concludes, when these residues are chemically characterized that they are toxicologically insignificant, the requirement for chronic feeding, oncogenic, metabolism, and reproduction studies will be waived. If no determination can be made that these unidentifed residues are toxicologically insignificant, the Agency may require chronic feeding, oncogenic, metabolism, and reproduction studies.

3) The results of the literature review indicated potential phosphine residues at levels below the established tolerance on processed foods and animal feed. Although there are no data establishing the fate of such minute residues, phosphine oxidizes readily to the relatively innocuous oxy-acids of phosphorus. Consequently, the Agency has reserved the requirements for animal metabolism on phosphine, and the data on storage stability of the sample to be analyzed, until the unidentified residues are identified. If the Agency cannot determine if these unidentified residues are toxicologically insignificant, the Agency may require the animal metabolism and storage stability data.

4) The Agency has considered any product containing aluminum phosphide to be as highly toxic as the phosphine gas which is liberated from aluminum phosphide and has placed these products in Toxicity Category I for labeling purposes based on acute and subchronic inhalation studies. The usual toxicity studies to rate aluminum phosphide products for other categories based on dermal, eye, or oral effects appear unwarranted. Thus, the Agency is waiving all of the acute toxicity studies for all aluminum phosphide products.

E. Criteria for Registration Under the Standard

To be subject to this Standard, aluminum phosphide products must meet the following conditions:

- contain aluminum phosphide as the sole active ingredient which generates the fumigant, phosphine, and have the same use patterns described in this Standard;

- bear required labeling; and

- conform to the acute toxicity limits, product composition, and use pattern requirements stated below.

The applicant for registration or reregistration of aluminum phosphide products subject to this Standard must comply with all terms and conditions described in this Standard, including a commitment to fill data gaps on a time schedule specified by the Agency as indicated in the Guidance Package and, when applicable, offer to pay compensation to the extent required by Sections 3(c)(1)(D) and 3(c)(2)(D) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, 7 U.S.C. 136(c)(1)(D) and 136(c)(2)(D). As discussed in Part I and in the Guidance Package, applicants for registration of aluminum phosphide products under this Standard must contact the Agency for specific instructions, including updated information on data requirements, and contact companies whose data may be cited and to whom compensation must be offered.

1. Manufacturing-Use Aluminum Phosphide Products

Although there are no manufacturing-use aluminum phosphide products registered with the Agency, the Agency has considered registration of these products as indicated below:

a. Acceptable Ranges and Limits

i. Product Composition Range

To be covered under this Standard, manufacturing-use aluminum phosphide products must conform to the requirements stated below:

Active Ingredient: Any percentage acceptable.

ii. Acute Toxicity Limits

The Agency woll consider registration of manufacturing-use aluminum phosphide products in the toxicity categories indicated by a "yes:"

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

iii. Use Patterns

To be covered under this Standard, manufacturing-use aluminum phosphide products must be labeled to allow for formulation into end-use fumigants which are intended only for one or a combination of the following use patterns:

1) Food/Feed, Nondomestic, Indoor Use (raw agricultural commodities)
2) Food/Feed, Nondomestic, Indoor Use (animal feed)
3) Food/Feed, Nondomestic, Indoor Use (processed commodities)
4) Nonfood/Nonfeed, Nondomestic, Indoor Use (including tobacco)
5) Nonfood/Nonfeed, Nondomestic, Outdoor Use (rodent control)

iv. Required Labeling

All manufacturing-use aluminum phosphide products must bear appropriate labeling as specified in 40 CFR 161.10. The Agency may, after review of data to be submitted under this Standard, impose additional labeling requirements.

2. End-Use Aluminum Phosphide Products

a. Acceptable Ranges and Limits

i. Product Composition Range

To be covered under this Standard, end-use aluminum phosphide products must conform to the requirements stated below:

Active Ingredient:	Any percentage acceptable.
Inert Ingredient:	Only those inert ingredients which are exempt from the requirements of a tolerance [see 40 CFR Section 180.1001 (c)] are acceptable for use on raw agriculture commodities, processed food, or animal feed. There are no restrictions on the percentages of inerts currently being used to formulate the end-use products included in this Standard.

ii. Acute Toxicity Limits

Because the fumigant in this pesticide is acutely toxic, all uses are restricted to certified applicators. The Agency will consider registration of end-use aluminum phosphide products in the toxicity categories indicated by a "yes:"

	I	II	III	IV
Acute oral toxicity	yes	yes	yes	yes
Acute dermal toxicity	yes	yes	yes	yes
Acute inhalation toxicity	yes	yes	yes	yes
Primary eye irritation	yes	yes	yes	yes
Primary dermal irritation	yes	yes	yes	yes

iii. Use Patterns

To be covered under this Standard, end-use aluminum phosphide products formulated as pellets, tablets or dusts must be labeled as a fumigant for one or more of the following uses*:

1) Food/Feed, Nondomestic, Indoor Use (raw agricultural commodities)
2) Food/Feed, Nondomestic, Indoor Use (animal feed)
3) Food/Feed, Nondomestic, Indoor Use (processed commodities)
4) Nonfood/Nonfeed, Nondomestic, Indoor Use (including tobacco)
5) Nonfood/Nonfeed, Nondomestic, Outdoor Use (rodent control)

iv. Required Labeling

All aluminum phosphide end-use products must bear appropriate labeling as specified in 40 CFR 161.10**. The Agency may, after review of data to be submitted under this Standard, impose additional labeling requirements. Currently, all registered aluminum phosphide products labeling contain adequate specialized statements regarding the use of protective clothing, appropriate application rates, notification of appropriate authorities when applying the product, safe disposal of spent aluminum phosphide residues, and other labeling required specifically for aluminum phosphide. There is much specialized labeling for aluminum phosphide which is contained on all currently registered products. Only a few of specialized labeling will be indicated below.

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* A comprehensive description of application rates, sites, pests and limitations that the Agency has accepted can be found in the Agency's Registration Standard Aluminum Phosphide Index Entry (EPA, 1981).

** The aluminum phosphide products should also conform to the June 5, 1980 Federal Register notice (45 FR 37884) announcing the initiation of the Label Improvement Program. On December 4, 1980, the Office of Pesticide Programs, EPA, requested that registrants having registered products containing aluminum phosphide modify their labels if the product has use directions for the fumigation of boxcars, hopper cars, railroad cars, vans, trailers, trucks, structures, warehouses, food processing plants, barges or on shipboard (in transit or shiphold). The labels of the currently registered products containing aluminum phosphide have been updated to the Agency's labeling requirements.

Residue Chemistry Statements

For those aluminum phosphide end-use products for use on foods and feeds, the following statements concerning aeration of the fumigated commodity must continue to appear on the labeling to prevent the established tolerances from being exceeded:

> "Fumigated foods and feeds shall be aerated for at least two days (48 hours)."
>
> "Tobacco, when fumigated in warehouse or under tarpaulin, shall be aerated for at least two days (48 hours), but when fumigated in hogsheads the aeration time shall be at least 72 hours."

Because aluminum phosphide end-use products must not be added directly to processed foods during the fumigation process, the following precautionary statements must continue to appear on the labeling to prevent contamination of these commodities:

> "Under no condition should any processed food, feed or tobacco be permitted to come into contact with aluminum phosphide or with the residues of spent aluminum phosphide except when added directly to processed brewer's rice, malt, and corn grits stored by breweries for use in the manufacturing of beer."

The following statements must continue to appear on the labeling where aluminum phosphide pellets or tablets are used with moisture permeable envelopes to ensure proper disposal of the pesticide and to preclude phosphine exposure to commodity retailers:

> "When pellets (or tablets) of aluminum phosphide are placed in moisture permeable envelopes, the envelopes shall be fastened to a substantial support; place no more than 10 pellets (no more than 2 tablets) into one envelope."
>
> "Aluminum phosphide shall not be placed in or attached to packages or cartons intended for retailers."

Ecological Effects Statements

The Environmental Hazards section of the labeling for rodenticide uses of aluminum phosphide must include the following statement:

> "This product is highly toxic to wildlife and fish. All burrows should be checked for signs of nontarget animals and if they are present, burrows should not be treated."

Because the rodenticide use of aluminum phosphide end-use products may be hazardous to a number of nontarget mammalian, avian, and reptilian species, the following statements must appear in the precautionary section of the labeling under the heading "Endangered Species Consideration:"

1) Black-Footed Ferret:

> "Do not use this product in the range of the Black-Footed Ferret. Contact the nearest U.S. Fish and Wildlife Service Office (Endangered Species Specialist) before the product is used. They will arrange for a ferret survey of the proposed use site."

2) Utah Prairie Dog:

> The directions for use for controlling prairie dogs must include the following restriction: "except Utah prairie dogs."

3) San Joaquin Kit Fox:

> "This pesticide should not be used within 1 mile of active dens of the San Joaquin Kit Fox in the following California counties: Kern, Kings, Fresno, San Luis Obispo, Merced, Monterey, Santa Barbara, Ventura, Tulare, and San Benito. Prior to use, contact the California Department of Fish and Game for recommendations."

4) Blunt-Nosed Leopard Lizard:

> "This pesticide should not be used in the range of the blunt-nosed leopard lizard in the following California counties: Kern, Fresno, Kings, Madera, Merced, and Tulare. Prior to use, contact the California Department of Fish and Game for recommendations."

5) Eastern Indigo Snake:

> "Do not use this product in the range of the Eastern Indigo snake in the following states: Mississippi, Alabama, South Carolina, Georgia, and Florida."

6) Desert Tortoise:

> "This pesticide should not be used in the Critical Habitat of the Beaver Dam slope population of the desert tortoise in Utah. This comprises an area extending from the southwest facing slope of the Beaver Dam Mountains, across Highway 91, west along the Arizona border and 10 miles to the Nevada border."

Toxicology Statements

Because the labeling for the currently registered end-use products contains sufficient specialized precautionary statements regarding complete application procedures, the use of protective clothing and respirator, and updated precautions required for aluminum phosphide under the Agency's Label Improvement

Program, the labeling of the various aluminum phosphide end-use formulations should continue to include the following statements for all uses:

"RESTRICTED USE PESTICIDE"

> "For retail sale to and use only by certified applicators or persons under their direct supervision and only those uses covered by the certified applicator's certification."
>
> "Not for use or storage in or around inhabited areas."

F. Tolerance Reassessment

1. Tolerances in the United States

The tolerances established for aluminum phosphide in or on raw agricultural commodities (40 CFR Section 180.225) for residues of the fumigant, phosphine, are as follows:

Commodity	Residue in ppm
Almonds	0.1
Barley	0.1
Beans, cocoa	0.1
Beans, coffee	0.1
Cashews	0.1
Corn	0.1
Corn, pop	0.1
Cottonseed	0.1
Dates	0.1
Filberts	0.1
Millet	0.1
Nuts, Brazil	0.1
Nut, pistachios	0.1
Oats	0.1
Peanuts	0.1
Pecans	0.1
Rice	0.1
Rye	0.1
Safflower	0.1
Sorghum	0.1
Soybeans	0.1
Sunflower, seed	0.1
Vegetables, seed and pod (except soybeans)	0.01
Walnuts	0.1
Wheat	0.1

Tolerances have been established for aluminum phosphide in processed foods (21 CFR Section 193.20) and animal feeds (21 CFR Section 561.40) for residues of the fumigant, phosphine. Such residues may not exceed 0.01 ppm on processed foods and 0.1 ppm on animal feed.

2. Canadian and Codex Tolerances

Although not officially accepted, CODEX has recommended phosphine tolerances as follows:

Commodity	Residue in ppm
Cereals, raw	0.1
Flour and other milled products	0.01
Dried vegetables	0.01
Spices	0.01
Breakfast cereals	0.01

In Canada, residues of phosphine >0.1 ppm are not permitted in raw cereals, soybeans, processed food, or animal feeds.

The residue data supporting the use of aluminum phosphide as a source of the fumigant, phosphine, are extensive and adequate (see Part VI, Residue Chemistry). Although these data include occasional reports of phosphine residues which exceed the established tolerances, the higher residues are considered aberrant and due to technical difficulties associated with an analysis for minute (<0.1 ppm) residues of phosphine. It is also possible that a component of the unidentified residue(s) which occurs as the result of a reaction between phosphine and constituents of fumigated commodities interferes with the analysis for phosphine. Based on the established tolerances, the theoretical human dietary exposure to phosphine residues is calculated to be 0.040 mg/day (theoretical maximum residue contribution: TMRC). These phosphine residues consist of oxy-acids of phosphorus (phosphoric, phosphorous, and hypophosphorous) which the Agency considers toxicologically insignificant and about 0.7 ppm uncharacterized residues, which have not been identified. If the Agency cannot determine that these uncharacterized residues are toxicologically insignificant, the Agency may require chronic feeding, oncogenic, metabolism and reproduction studies (see Part VI.F, Toxicology).

III. Summary of Data Requirements

A. Introduction

Applicants for registration of end-use aluminum phosphide products must cite or submit the information identified as required in the tables in this Part. The tables applicable to end-use products indicate whether the product to be tested is the technical grade or the formulation. Data generated on one formulation may be used to satisfy the data requirement for a substantially similar formulation, based on the chemical composition as indicated by the Confidential Statement of Formula (CSF). Information on which product-specific data requirements are already satisfied is available in the Guidance Package and in Table III.B and C of this Standard.

Preceding each requirement, with the exception of Residue Chemistry, are listed the Proposed Guidelines which describe the type of data and when the data are required to be submitted. Justification for the test requirement is provided in the Guidelines (see 43 FR 29696 of July 10, 1978 and 43 FR 37336 of August 22, 1978). A discussion of why data additional to that already specified in the Guidelines are necessary, or why data usually required are not necessary for this chemical, is explained in footnotes to the tables. Areas where additional data may be required as the result of tiered testing are indicated.

Bibliographic citations in the following tables indicate that the study listed accomplishes one of the following:

1) provides all the information required by the guideline requirement; or
2) provides partial information required by the guideline requirement which is elaborated on by an accompanying footnote.

The word "yes" under the heading "Does EPA have data to partially or totally satisfy this requirement?" means that the requirement has been fully satisfied, unless otherwise noted.

B. Generic Data Requirements, Table III.A

This table discusses those data that pertain to the properties or effects of aluminum phosphide as an active ingredient. Thus, these data are relevant to an evaluation of the risks of all products containing aluminum phosphide. Providing data to fill generic data requirements is generally the responsibility of the registrant(s) of manufacturing-use aluminum phosphide products. However, because there are no manufacturing-use products registered, the registrants of end-use aluminum phosphide products must assume this responsibility.

Registrants of end-use products containing aluminum phosphide are advised that if the Agency does not receive commitments within 90 days of receipt of the Guidance Package that they will fill data gaps identified in Table III.A, the end-use product registrations may be suspended.

Applicants for registration or reregistration of end-use aluminum phosphide products must acknowledge reliance on existing data which fill indicated data requirements under FIFRA Section 3(c)(1)(D). These data are listed under the column "Bibliographic Citation" in Table III.A.

C. Product-Specific Data Requirements for Manufacturing-Use, Table III.B, and End-Use Aluminum Phosphide Products, Table III.C

These tables discuss those data that relate only to the properties or effects of a product with a specific composition (or substantially similar composition). Thus, these data are required of each formulation (or substantially similar product) to characterize the product's particular composition and physical/chemical properties, and to characterize the product's acute toxicity. Providing data to fulfill these requirements is the responsibility of each applicant for the registration or reregistration of a manufacturing-use or an end-use aluminum phosphide product. If the Agency has data which fulfill this requirement for a particular product(s), this is indicated in the table and in the Guidance Package accompanying this Standard.

Product-specific data may be acknowledged under FIFRA Section 3(c)(1)(D) only if the Agency has established that one product is substantially similar to another product for which the Agency has received acceptable data.

Table III.A-1 Generic Data Requirements for Aluminum Phosphide, Product Chemistry (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-3	Product Identity:					
	- Identity of ingredients	yes	Technical grade of active ingredient	partial[1/]	000005762	yes/8 months
	- Statement of composition	yes		partial[1/]	000005762	yes/8 months
163.61-4	Manufacturing process, described	yes	Technical grade of active ingredient	partial[2/]	005010196, 000005762, 005007199	yes/8 months
163.61-5	Discussion on formation of impurities	yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-6	Certified limits: - Actives, all - Impurities >0.1%	 yes yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-7	- Analytical methods	yes	Technical grade of active ingredient	partial[1/]	005010196, 000005762, 000005696, 000005746, 000005675	yes/8 months
	- Composition data	yes	Technical grade of active ingredient	partial[1/]	000005696	yes/8 months
163.61-8(c)(1)	Color	yes	Technical grade of active ingredient	partial[1/]	000005762, 000005911, 005007617	yes/8 months

Table III.A-1 Generic Data Requirements for Aluminum Phosphide, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(c)(2)	Odor	yes	Technical grade of active ingrdient	partial[1]	000005762	yes/8 months
163.61-8(c)(3)	Melting Point	yes	Technical grade of active ingredient	partial[1]	000005762, 000005746	yes/8 months
163.61-8(c)(4)	Solubility	yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-8(c)(5)	Stability	yes	Technical grade of active ingredient	no	-	yes/8 months
163.61-8(c)(6)	Octanol/Water Partition Coefficient	no[3]				
163.61-8(c)(7)	Physical State	yes	Technical grade of active ingredient	yes	005010196, 000005746	no
163.61-8(c)(8)	Density or Specific Gravity	yes	Technical grade of active ingredient	partial[1]	000005762, 000005746	yes/8 months

Table III.A-1 Generic Data Requirements for Aluminum Phosphide, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8(c)(9)	Boiling Point	no[3]				
163.61-8(c)(10)	Vapor Pressure	no[3]				
163.61-8(c)(11)	pH	no[3]				

1/ Even though some of the data rquirements have been partially or completely fulfilled for some technical grade of active ingredients used to formulate end-use products, the Agency has not received data to support all end-use products. These data requirements must be met by each applicant at the time of registration or reregistration. Note: Currently, no technical grade of the active ingredient is registered.

2/ A submission by Degesch (MRID #000005672) indicates how their technical grade of aluminum phosphide is manufactured, but the discussion is not sufficiently detailed . A description is required for the manufacturing procees used to produce each technical grade of aluminum phosphide used in each registered end-use product.

3/ These physical/chemical property data requirements are not needed to support the registration of products under this Standard for the following reasons: 1) property #6 (Octanol/Water Partition Coefficient) is not required for inorganic compounds ; 2) properties #9 (Boiling Point) and #10 (Vapor Pressure) are not required for solids; however, the compound melts above 1,000°C: and 3) property #11 (pH) is not required because the end-use products do not dissolve, but instead react with water to liberate phosphine gas (PH_3), and the technical grade of aluminum phosphide decomposes in water to PH_3 and $Al(OH)_3$.

Table III.A-2 Generic Data Requirements for Aluminum Phosphide, Environmental Fate (see Part V)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.62-7(b)	Hydrolysis[1/]	yes	Phosphine[2/]	no	-	yes/14 months
163.62-8(f)	Microbial metabolism (3) effects of pesticides on microbes	yes	3/	no	-	3/
163.62-8(g)	Activated sludge metabolism	yes	3/	no	-	3/
163.62-9(c)	Volatility[1/]	yes	Phosphine[2/]	no	-	yes/14 months
163.62-12	Reentry[1/]	yes	Phosphine[2/]	partial[4/]	000005735, 000005691, 000005737, 000005662, 000005797, 000005664	yes/14 months
163.62-13	Disposal and Storage	no[5/]				

Table III.A-2 Generic Data Requirements for Aluminum Phosphide, Environmental Fate (see Part V) (cont'd)

1/ While the available phosphine toxicology studies are inadequate, the Agency believes that in most cases the actual exposure to phosphine is sufficiently low that a worst case analysis will support present uses of aluminum phosphide in the absence of additional phosphine toxicology studies. However, the Agency requires additional exposure monitoring data to support the conclusion that current levels of phosphine exposure are toxicologically insignificant. Therefore, for each site or similar group of sites for which entry into treated (confined) areas is likely, the Agency requires adequate exposure monitoring data. Data should measure the actual concentration(s) of phosphine to which workers will be exposed following reentry into treated (confined) areas when following accepted aluminum phosphide label directions. To preclude unnecessary studies from being conducted, the registrant is strongly urged to consult with appropriate Agency scientists (i.e., Hazard Evaluation Division, Office of Pesticide Programs) before initiating the phosphine exposure monitoring studies. For useful background information, consult the reference to hydrolysis and volatility in the Agency's Guidelines.

2/ Because aluminum phosphide reacts with water to release the fumigant, phosphine, studies should analyze for phosphine concentrations.

3/ The requirement for submission of these data is currently being reserved pending the review and modification of testing protocols. Because the use patterns (enclosed areas) currently registered are not similar to other agricultural pesticides (outdoor), the Agency is re-examining the need for these data requirements.

4/ The kinetics of phosphine release and dissipation cannot be determined quantitatively from these studies.

5/ Data necessary to meet this requirement will be provided by data from Section 163.62-7(b), 163.62-8(f)(3), and 163.62-8(g).

Table III.A-3 Generic Data Requirements for Aluminum Phosphide, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-1	Acute Oral Toxicity	yes	Technical grade of active ingredient	no	-	no[1]
163.81-2	Acute Dermal Toxicity	yes	Technical grade of active ingredient	no	-	no[1]
163.81-3	Acute Inhalation Toxicity	yes	Technical grade of active ingredient	partial[2]	005007354	no[1]
163.81-4	Primary Eye Irritation	yes	Technical grade of active ingredient	no	-	no[1]
163.81-5	Primary Dermal Irritation	yes	Technical grade of active ingredient	no	-	no[1]
163.81-6	Dermal Sensitization	no[3]				
163.81-7	Acute Delayed Neurotoxicity	no[4]				

Table III.A-3 Generic Data Requirements for Aluminum Phosphide, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.82-1	Subchronic Oral	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.82-2	Subchronic Dermal	no[3/]				
163.82-4	Subchronic Inhalation	yes	Technical grade of active ingredient	no	-	reserved[6/]
163.82-5	Subchronic Neurotoxicity	no[4/]				
163.83-1	Chronic Feeding Study	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.83-2	Oncogenicity	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.83-3	Teratogenicity	yes	Technical grade of active ingredient	no	-	reserved[6/]

Table III.A-3 Generic Data Requirements for Aluminum Phosphide, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.82-4	Reproduction	yes	Technical grade of active ingredient	no	-	reserved[5/]
163.84-1 163.84-2 163.84-3 163.84-4	Mutagenicity	yes	Technical grade of active ingredient	no	-	reserved[6/]
163.85-1	Metabolism	yes	Radiolabeled analytical grade	no	-	reserved[6/]

1/ The acute toxicity studies are required for labeling purposes. The severest labeling restriction (i.e, the signal word DANGER and skull and crossbones) have been imposed on the end-use aluminum phosphide products due to the highly acute inhalation toxicity of phosphine which can be readily evolved from the formulation. Therefore, all of the acute toxicity requirements on the technical grade of active ingredient products have been waived.

2/ This study was considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

3/ This study is required when repeat dermal exposures are expected with the end-use products. There is expected to be no dermal exposure to these formulations.

4/ Aluminum phosphide or phosphine are not organophosphorus compounds nor do they produce cholinesterase inhibition.

5/ These requirements are being reserved until the Agency receives and reviews the residue chemistry data (e.g., identification of unknown residues). If the Agency determines that these unidentified phosphine residues are toxicologically significant, these studies may be required.

6/ These requirements are being reserved until the Agency receives and reviews the required environmental fate data (e.g. volatility and reentry). If there is any exposure to phosphine during reentry, the Agency may require these studies.

Table III.A-4 Generic-Data Requirements for Aluminum Phosphide, Residue Chemistry (see Part VII)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
-	Nature of the Residue	yes	-	partial[1/]	005018681, 005008303, 005007621, 005008840, 005015384, 005013027, 005020467, 000005813, 005012115	yes/12 months
-	Metabolism in Animals	no[2/]				
-	Analytical Methods	yes	-	yes	005007190, 005007724,[3/] 005007845	no
-	Residue Data:					
	1. Raw Agricultural Commodities	yes	-	yes	005007190, 000006724, 005013439, 005016260, 005022032, 000005750, 005013276, 000005671, 005012293, 000005905, 000005767, 000005719, 005007845, 000005685, 000005935, 005007830, 005019407, 005014054, 000005686, 000005781, 000005783, 005020562, 005020467, 005016893, 000005696, 005015520	no

Table III.A-4 Generic-Data Requirements for Aluminum Phosphide, Residue Chemistry (see Part VII) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Compostion	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
-	Residue Data (cont'd):					
	2. Processed Foods and Feeds	yes	-	yes	000005750, 000005775, 000022007, 000022026, 000005776, 000005774, 000005786, 000022008, 000005696, 000022015, 000022017, 005012293, 000005777, 000005768, 000005905, 005007190, 000005935, 000020578, 005022032, 000022913	no
	3. Milk, Meat, Eggs and Poultry	no[2/]				
-	Residue Data Following Aeration of Commodity	yes	-	yes	000020578, 000022017, 000005686	no
-	Storage Stability Data for Residues in Commodities	no[2/]				

Table III.A-4 Generic-Data Requirements for Aluminum Phosphide, Residue Chemistry (see Part VII) (cont'd)

1/ In support of this Standard, recent studies (see Part VII), conducted with radiolabeled phosphine (^{32}P), were reviewed which indicate phosphine reacts irreversibly with grain and other fumigated commodities to form oxy-acids of phosphorous and unidentified, water-insoluble, residue(s). The Agency is therefore requesting further study on the nature of the residue, specifically that the unidentified residue (ca 0.7 ppm) be identified. After reviewing the requested data, if the Agency cannot determine that these unidentified residues are toxicologically insignificant, the Agency may requested additional studies to support the continued registration of aluminum phosphide products (refer to those data requirements indicated by footnote #2).

2/ Because of the very small residues of phosphine which result from the currently accepted uses of aluminum phosphide, the fugitive nature of phosphine per se, and the labeling restriction against mixing the end-use products with animal feeds, the Agency will not require these data at this time. However, if the Agency determines that these unidentified residues are toxicologically significant, these studies may be required.

3/ An acceptable analytical method can also be found in Volume II of the Pesticide Analytical Manual (PAM), Pesticide Reg. Sec. 180.225, 1981 Edition (Note: PAM is published and revised periodically by the Food and Drug Administration).

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Table III.B-1 Product-Specific Data Requirements for Aluminum Phosphide Manufacturing-Use Products, Product Chemistry (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-3	Product Identity:					
	- Identity of ingredients	yes	Each manufacturing-use product	no	-	yes/8 months[1]
	- Statement of composition	yes		no	-	yes/8 months[1]
163.61-4	Manufacturing process, described	yes	Each manufacturing-use product	no	-	yes/8 months[1]
163.61-5	Discussion on formation of impurities	yes	Each manufacturing-use product	no	-	yes/8 months[1]
163.61-6	Certified limits:		Each manufacturing-use product			
	- Actives, all	yes		no	-	yes/8 months[1]
	- Impurities >0.1%	yes		no	-	yes/8 months[1]
163.61-7	- Analytical methods	yes	Each manufacturing-use product	partial[2]	005010196, 000005762, 000005696, 000005746, 000005675	yes/8 months[1]
	- Composition data	yes	Each manufacturing-use product	partial[2]	000005696	yes/8 months[1]

Table III.B-1 Product-Specific Data Requirements for Aluminum Phosphide Manufacturing-Use Products, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8 Physical/Chemical Property Data[3]						
-8(c)(1)	Color	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(2)	Odor	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(8)	Density	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(11)	pH	no[4]				
-8(c)(12)	Storage Stability	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(13)	Flammablility	yes[4]	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(14)	Oxidizing/Reduction	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(15)	Explosiveness	yes	Each manufacturing-use product	no	-	yes/8 months[1]

Table III.B-1 Product-Specific Data Requirements for Aluminum Phosphide Manufacturing-Use Products, Product Chemistry (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8 Physical/Chemical Property Data (cont'd)[3]						
-8(c)(16)	Misciblility	no[4]				
-8(c)(17)	Viscosity	no[4]				
-8(c)(18)	Corrosion Characteristics	yes	Each manufacturing-use product	no	-	yes/8 months[1]
-8(c)(19)	Dielectric Breakdown Voltage	no[4]				

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[1] Even though some of the requirements have been partially or completely fulfilled for some products, references cannot be cited to support other products, except for 163.61-7. These data are not required to be submitted since there are currently no manufacturing-use products registered; data indicated will be required to support the registration of each such product at the time of registration. Note: The data requirements for products intended for manufacturing-use and those end-use products produced by an intergrated-formulation system are the same.

[2] The Agency has information to support some products. Data must be submitted for other manufacturing-use products.

[3] For the technical aluminum phosphide used to formulate the manufacturing-use product, data are also required for the physical/chemical properties as indicated in Table III.A-1.

[4] These physical/chemical property data requirements are not needed to support the registration of products under this Standard for the following reasons: 1) property #11 (pH) is not required because the products do not dissolve, but instead react with water to liberate phosphine gas (PH_3), and the aluminum phosphide decomposes in water to PH_3 and $Al(OH)_3$; 2) property #13 (Flammability) is normally required only for flammable liquids. (However, aluminum phosphide is classified by the U.S. Dept. of Transportation as a flammable solid and flammability data are not required for unregistered technical chemicals. These data will be needed for manufacturing-use products of aluminum phosphide); 3) properties #16 (Miscibility) and #17 (Viscosity) are required only for liquids; and 4) property #19 (Dielectric Breakdown Voltage) is not required because the product is not applied directly to electrical wires.

Table III.B-2 Product-Specific Data Requirements for Manufacturing-Use Aluminum Phosphide Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-1	Acute Oral Toxicity	yes	Each manufacturing-use product	no	-	no[1]
163.81-2	Acute Dermal Toxicity	yes	Each manufacturing-use product	no	-	no[1]
163.81-3	Acute Inhalation Toxicity	yes	Each manufacturing-use product	partial[2]	005007354	no[1]
163.81-4	Primary Eye Irritation	yes	Each manufacturing-use product	no	-	no[1]
163.81-5	Primary Dermal Irritation	yes	Each manufacturing-use product	no	-	no[1]
163.81-6	Dermal Sensitization	no[3]				

Table III.B-2 Product-Specific Data Requirements for Manufacturing-Use Aluminum Phosphide Products, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-7	Acute Delayed Neurotoxicity	no[4/]				

1/ The acute toxicity studies are required for labeling purposes. The severest labeling restriction (i.e, the signal word DANGER and skull and crossbones) have been imposed on the end-use aluminum phosphide products due to the highly acute inhalation toxicity of phosphine which can be readily evolved from the formulation. Therefore, all of the acute toxicity requirements on the manufacturing-use products have been waived.

2/ This study was considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

3/ This study is required when repeat dermal exposures are expected. There is expected to be no dermal exposure to these formulations.

4/ Aluminum phosphide or phosphine are not organophosphorus compounds nor do they produce cholinesterase inhibition.

Table III.C-1 Product-Specific Data Requirements for Aluminum Phosphide End-Use Products, Product Chemistry[1] (see Part IV)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-3	Product Identity:					
	- Identity of ingredients	yes	Each end-use product	yes[2]	-	no
	- Statement of composition	yes		yes[2]	-	no
163.61-4	Manufacturing process, described	yes	Each end-use product	partial[3]	000005762, 000005746 000005696	yes/8 months
163.61-5	Discussion on formation of impurities	yes	Each end-use product	no	-	yes/8 months
163.61-6	Certified limits:		Each end-use product			
	- Actives, all	yes		no	-	yes/8 months
	- Impurities > 0.1%	yes		no	-	yes/8 months
163.61-7	- Analytical methods	yes	Each end-use product	partial[4]	000005696, 000005746, 000005762, 005010196, 000005675, 000005761	yes/8 months
	- Composition data	yes	Each end-use product	partial[4]	000005696	yes/8 months

Table III.C-1 Product-Specific Data Requirements for Aluminum Phosphide End-Use Products, Product Chemistry[1] (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8	Physical/Chemical Property Data					
-8(c)(1)	Color	yes	Each end-use product	partial[4]	000005907	yes/8 months
-8(c)(2)	Odor	yes	Each end-use product	partial[4]	000005907, 005007818	yes/8 months
-8(c)(8)	Density or Bulk Density	yes	Each end-use product	no	-	yes/8 months
-8(c)(11)	pH	no[5]				
-8(c)(12)	Storage Stability	yes	Each end-use product	partial[4]	000005759, 000005760, 000005763, 000005746	yes/8 months
-8(c)(13)	Flammablility	yes[5]	Each end-use product	partial[4]	000005675, 000005681, 000005813, 000005669, 005020086	yes/8 months
-8(c)(14)	Oxidizing/Reduction	yes	Each end-use product	no	-	yes/8 months
-8(c)(15)	Explosiveness	yes	Each end-use product	no	-	yes/8 months
-8(c)(16)	Miscibility	no[5]				
-8(c)(17)	Viscosity	no[5]				

Table III.C-1 Product-Specific Data Requirements for Aluminum Phosphide End-Use Products, Product Chemistry[1] (see Part IV) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.61-8 Physical/Chemical Property Data (cont'd)						
-8(c)(18)	Corrosion Characteristics	yes	Each end-use product	no	-	yes/8 months
-8(c)(19)	Dielectric Breakdown Voltage	no [5]				

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[1] Even though some of the requirements have been partially or completely fulfilled for some products, references cannot be cited to support other products, except for 163.61-7. These requirements must be submitted by each applicant at the time of registration or reregistration. Data indicated in Table III.A-1 will also be required to support the registration of each end-use product since no technical grade or manufacturing-use products are registered. The data requirements for products intended for manufacturing-use and those end-use products produced by an intergrated-formulation system are the same.

[2] The Agency has information to support all currently registered end-use products [information was provided in the Confidential Statements of Formula (CSF)].

[3] The discussion on descriptions of the manufacturing process used to formulate the end-use products are not sufficiently detailed.

[4] The Agency has information to support some products. These data must be submitted for other end-use products.

[5] These physical/chemical property data requirements are not needed to support the registration of products under this Standard for the following reasons: 1) property #11 (pH) is not required because the end-use products do not dissolve, but instead react with water to liberate phosphine gas (PH_3), and the technical grade of aluminum phosphide decomposes in water to PH_3 and $Al(OH)_3$; 2) property #13 (Flammablility) is normally required only for flammable liquids. (However, alumnium phosphide is classified by the U.S. Dept. of Transportation as a flammable solid and flammablility data will be needed.); 3) properties #16 (Miscibility) and #17 (Viscosity) are required only for liquids; and 4) property #19 (Dielectric Breakdown Voltage) is not required because the product is not applied directly to electrical wires.

Table III.C-2 Product-Specific Data Requirements for End-Use Aluminum Phosphide Products, Toxicology (see Part VI)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-1	Acute Oral Toxicity	yes	Each end-use product	no	-	no[1]
163.81-2	Acute Dermal Toxicity	yes	Each end-use product	no	-	no[1]
163.81-3	Acute Inhalation Toxicity	yes	Each end-use product	partial[2]	005007354	no[1]
163.81-4	Primary Eye Irritation	yes	Each end-use product	no	-	no[1]
163.81-5	Primary Dermal Irritation	yes	Each end-use product	no	-	no[1]
163.81-6	Dermal Sensitization	no[3]				

Table III.C-2 Product-Specific Data Requirements for End-Use Aluminum Phosphide Products, Toxicology (see Part VI) (cont'd)

Guidelines Citation	Name of Test	Are Data Required for this Standard?	Composition	Does EPA Have Data to Partially or Totally Satisfy this Requirement?	Bibliographic Citation (MRID #)	Must Additional Data be Submitted under FIFRA 3(c)(2)(B)? If so, months allowed for submission from published date of Standard.
163.81-7	Acute Delayed Neurotoxicity	no[4/]				

1/ The acute toxicity studies for end-use products are required for labeling purposes. The severest labeling restriction (i.e, the signal word DANGER and skull and crossbones) have been imposed on the end-use aluminum phosphide products due to the highly acute inhalation toxicity of phosphine which can be readily evolved from the formulation. Therefore, all of the acute toxicity requirements on the end-use products have been waived.

2/ This study was considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

3/ This study is required when repeat dermal exposures are expected. There is expected to be no dermal exposure to these formulations.

4/ Aluminum phosphide or phosphine are not organophosphorus compounds nor do they produce cholinesterase inhibition.

IV. Product Chemistry

A. Introduction

FIFRA 3(c)(2)(A) requires the Agency to establish guidelines for registering pesticides in the United States. Subpart D of these guidelines requires a registrant to provide data on the composition of his product and the physical and chemical properties of both the formulated product and the active ingredient(s) in the product. These data are needed by the Agency to characterize products and to assess environmental and health effects from their use.

To evaluate product composition, the Agency requires: 1) the submission of a detailed manufacturing process for pesticides including data on the composition of starting and intermediate materials; 2) a discussion of the presence in a product of unintentional ingredients formed during, or subsequent to, manufacture; 3) declaration of the upper and lower limits for each active and intentionally added inert ingredient, and the upper limit for each impurity; 4) certification that ingredient limits will be maintained for all quantities of the product sold or distributed in commerce; and 5) analytical methods, and data obtained by these methods, for each active ingredient and identifiable impurity at or in excess of 0.1% of the product weight. The Agency may require methods and data for impurities below 0.1% of the product weight when highly toxic impurities are present.

The Agency also requires data on the physical and chemical properties of the pesticide. For example, data are needed concerning the identity and physical state of the active ingredient (e.g., melting and boiling points, vapor pressure, and solubility). Data are also required on those properties of the formulated product that are clearly related to necessary labeling cautions (e.g., flammability, corrosion characteristics, and storage stability).

To assist applicants in meeting these requirements and to accelerate the Agency's review and evaluation of the submitted data, the guidelines include criteria for acceptable testing of products and an appendix with references to literature sources containing appropriate testing protocols.

B. Chemical Identity

In the United States, aluminum phosphide is the preferred name for the pesticide which is the subject of this Registration Standard. It is also the name recommended by both the U.S. Department of Transportation and the American Chemical Society's Chemical Abstracts Service (CAS). Additional identifying characteristics of aluminum phosphide include: molecular formula, AlP; CAS Registry No., 20859-73-8; and molecular weight, 57.95. Aluminum phosphide end-use products are imported into this country are produced in an intergrated-formulation system; some end-use products may be formulated in this country.

Although aluminum phosphide is stable when dry, it reacts with water, including atmospheric moisture, to liberate the fumigant phosphine [British Crop Protection Council (1974) Pesticide Manual]. The identifying characteristics of phosphine are: molecular formula, PH_3; molecular weight, 34.00; and CAS Registry No., 7803-51-2.

C. Manufacturing Process

The Agency has received inadequate information and data describing both the manufacturing process for technical aluminum phosphide (White and Bushey, 1953, MRID #00510196, DEGESCH America, Incorporated, 1977, MRID #000005762, and White and Bushey, 1944, MRID #005007199) and the formulating process for end-use aluminum phosphide products (DEGESCH America, Incorporated, 1977, MRID #000005762, Research Products Company, 19??, MRID #000005746, and Rosebrook, 1972, MRID #000005696). However, the product composition data contained in the manufacturing process are protected under Section 10 of the FIFRA.

All of the currently registered end-use products of aluminum phosphide are produced by means of an integrated-formulation system. In this type of formulation system, the unregistered technical material is formulated directly into an end-use product. The Agency requires for each such technical grade of aluminum phosphide a description of the manufacturing process*.

An adequate description must be sufficiently detailed to indicate whether the aluminum phosphide is produced by a continuous or batch process, provide information and data on the "beginning" or starting materials (their identity and composition), the manufacturing equipment, the physical conditions controlled during the process, and a flowchart listing the chemical reactions (and their duration) which are used to manufacture the aluminum phosphide. This description is also expected to indicate the steps taken to purify the technical chemical and the measures taken to assure the quality of the final end-use product.

D. Discussion on the Formulation of Impurities (and Unintentional Ingredients)

In accordance with Section 163.61-5 of the proposed product chemistry guidelines (July, 1978), the registration of each aluminum phosphide end-use product produced by an integrated-formulation system is to be supported by a discussion of the impurities that may be present in the product at a level equal to or greater than 0.1% (1,000 ppm). The discussion is expected to be based on established chemical theory and the required description of the manufacturing process (Section 163.61-4), with consideration given to the impurities present in both the manufacturing reactants and formulating materials. Data to meet this requirement have not been submitted to support the registration of any aluminum phosphide product.

E. Declaration and Certification of Ingredient Limits

The Confidential Statements of Formula for the products registered under this Standard (those containing aluminum phosphide as the sole source for generating the active agent, phosphine) should be revised to indicate upper and lower limits for both the aluminum phosphide and any intentionally added inerts which are $\geq$0.1%. Upper limits must also be stated for product impurities >0.1% and those known to be potentially hazardous regardless of concentration.

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* Currently there is no manufacturing-use aluminum phosphide products registered with the Agency.

F. Product Analytical Methods and Data

Official methods of analysis by the Association of Official Analytical Chemists (AOAC), or by similar organizations, have not been established for aluminum phosphide. However, the submissions reviewed for this Standard include analytical procedures for formulations. In these procedures, the aluminum phosphide content of the product is calculated on the basis of its phosphide content. This is accomplished by reacting the product with water and acid; the phosphide is converted to phosphine [$AlP + 3H_2O \longrightarrow PH_3 + Al(OH)_3$]; the phosphine is swept with nitrogen into an adsorption vessel containing a solution of mercuric (II) chloride; a reaction occurs [$PH_3 + 3HgCl_2 \longrightarrow P(HgCl)_3 + 3HCl$]; the hydrochloric acid produced is titrated with standard alkali; and the aluminum phosphide content is then calculated.

The basis of this procedure was suggested in 1953 (White and Bushey, 1953, MRID #005010196). Recently, a variation of this procedure, using dilute sulfuric acid to assure complete reaction of the aluminum phosphide (Rosebrook, 1972, MRID #000005696) was submitted to the Agency as the recommended procedure for analyzing some end-use formulations of aluminum phosphide. Typical aluminum phosphide product composition data determined by Rosebrook (1972, MRID #000005696) showed acceptable analytical results. Similar methodology is included in other submissions (DEGESCH America, Incorporated, 1977, MRID #000005762; Research Products Company, 19??, MRID #000005746; Wallis, 1964, MRID #000005675; and DEGESCH America, Incorporated, 1944?, MRID #000005761). (Note: The phosphine evaluation procedure as described in the "EPA Manual of Chemical Methods for Pesticides and Devices" is the recommended procedure for analyzing zinc phosphide. This method would also be applicable to aluminum phosphide with modifications.)

G. Physical and Chemical Property Data

The data requirements for the end-use products produced by an integrated-formulation system are properties #1, #2, and #7 through #19 in Table VI.A. For the unregistered technical grade of aluminum phosphide used to formulate such end-use products, data are required for properties #1 through #11. However, because of the special characteristics of aluminum phosphide, exceptions to these requirements have been made for this Standard. These exceptions are summarized in Table IV.A. The Agency does not have data to support all end-use products currently registered or information regarding each technical grade of aluminum phosphide used to formulate these end-use products.

TABLE IV.A

Physical/Chemical Properities for Aluminum Phosphide

Physical/Chemical Property	End-use products (MRID #)	Technical material (MRID #)
(1) Color	(000005907) 1/	Gray to yellow (000005762, 000005911, 005007617)
(2) Odor	(000005907, 1/ 005007818)	Data required (000005762)
(3) Melting point	Not required	>1,000°C (000005762, 000005746)
(4) Solubility	Not required	Data required 2/
(5) Stability	Not required	Data required 3/
(6) Octanol/Water partition coefficient	Not required	For polar or ionic inorganics; not required
(7) Physical state	Solids, all products (000005672)	Crystals; cubic zinc blend. (005010196, 000005746)
(8) Density Bulk density	Data required Data required	2.85 gm/cc 1.00 gm/cc (000005762, 000005746)
(9) Boiling point	Not required	Not required due to high melting point
(10) Vapor pressure	Not required	Not required due to high melting point
(11) pH	Not required	Insoluble; decomposes in water to PH_3 and $Al(OH)_3$
(12) Storage stability	>46 months 000005759, 000005760, 000005763, 000005746	Not required
(13) Flammability	Data required 4/	Not required 4/
(14) Oxidizing/Reduction Potential	Data required 4/	Not required

TABLE IV.A (Cont'd)

Physical/Chemical Properities for Aluminum Phosphide

Physical/Chemical Property	End-use products (MRID #)	Technical material (MRID #)
(15) Explosiveness	Data required 4/	Not required
(16) Miscibility	Not required; need for liquids only	Not required
(17) Viscosity	Not required; need for liquids only	Not required; liquids only
(18) Corrosion Characteristics	Data required	Not required
(19) Dielectric Constant Voltage	Not required; because the applicator does not directly applied AlP to electrical components	Not required

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1/ On the basis of the submitted Confidential Statements of Formula, the end-use products would be gray and relatively odorless; however, information on these properties is needed for each product.

2/ For the technical material, data are required for the solubility of aluminum phosphide in common laboratory solvents (e.g., chloroform and carbon disulfide) in accordance with guidelines.

3/ Data showing the effect of small amounts of impurities (alkali, acids, and metallic ions) on the stability of aluminum phosphide (technical) are required.

4/ While oxidizing/reduction and explosiveness data are required for aluminum phosphide in accordance with the guideline requirements, it should be noted that the principle flammability and explosion hazards of these products are associated with their reaction with moisture and the evolution of phosphine. Phosphine, like other ignitable gases, is explosive in air between certain concentrations. For phosphine these concentrations are, by volume, 1.79% to 1.89% (Dittmar, 1960, MRID #000005669). Note: Aluminum phosphide is classified by the U.S. Dept. of Transportation as a flammable solid and flammability data are not required for the technical chemical. Flammability data, however, will be needed for manufacturing-use products of aluminum phosphide.

In concentration of 1.79% to 1.89% by volume, phosphine air mixtures are explosive (Dittmar, 1960, MRID #000005669). The temperature needed to initiate ignition (which might be provided by a heated surface) is reported to range between 100°C to 150°C (Duford, 1961, MRID #000005681). This variation is reported to be dependant upon the presence of impurities [such as diphosphine; P_2H_3] in the evolved phosphine which, in turn, is dependent upon the purity of the aluminum phosphide (Fluck, 1973, MRID #000005813). Atmospheric moisture, and gases such as carbon dioxide and ammonia, which may be incorporated into the product as ammonia carbamate, are also reported to effect the ignition temperature.

Using an electric spark and conditions associated with the fumigation of wheat [i.e., humidity 15%, moisture in the wheat 9.4%, Phostoxin® tablets (0.19 gm AlP/meter^3)], Duford (1961, MRID #000005681) provided data indicating that under fumigation conditions, ignition of phosphine-air mixtures does not occur. Wallis (1964, MRID #000005675) also showed that under conditions typical to those associated with the fumigation of grains, phosphine-air mixtures are not flammable or explosive. These data, since its proprietary, are reported in the Confidential Appendix of this Standard (see Part IX).

H. Summary of Data Gaps

In accordance with the proposed product chemistry guidelines, additional data and information are required regarding the description of manufacturing process, discussion on formation of impurities, declaration and certification of ingredient limits, and product analytical methods. These information and data are required for all currently registered end-use products containing aluminum phosphide and for the technical grade of active ingredient used to formulate the end-use products. Physical/chemical data required for the technical grade of active ingredient are: color, odor, melting point, solubility, stability, and density or specific gravity. The physical/chemical data required for the currently registered end-use products by an intergrated-formulation system are: color, odor, density, storage stability, oxidizing/reduction, explosiveness and corrosion characteristics.

V. Environmental Fate

A. Use Summary

Aluminum phosphide is a fumigant registered for the control of insects, primarily Coleoptera and Lepidoptera, in raw agricultural commodities, processed food, animal feed, and nonfood/nonfeed products (including tobacco) stored in warehouses, grain elevators, and ships. Phosphine gas, generated from the reaction of aluminum phosphide with ambient moisture, is the toxic agent. Annual use of aluminum phosphide is approximately 0.5-1.0 million pounds of active ingredient. The major use sites are unprocessed agricultural commodities and tobacco (70-80%) and processed foods (15-25%).

Aluminum phosphide is available in pelleted/tableted (P/T) formulation with 55, 57, or 60% active ingredient or as a 57% active ingredient dust (D) preparation prepacked in special paper sackets (bags). Aluminum phosphide is applied by uniformly distributing the product (P/T or D) throughout the site or material to be fumigated. Pelleted/tableted products are inserted directly into the commodity to be treated, or the product is placed in moisture-permeable envelopes and/or cardboard trays which are placed on the floor or attached to a support timber or other support structure within the fumigation site. Dust products are distributed in gas-exchange bags (moisture-permeable envelopes). The specific application method is determined by the material to be fumigated and the available equipment. Label instructions require the collection and disposal of spent aluminum phosphide product after fumigation of processed foods and when gas-exchange bags or cardboard trays are used. Label instructions also require that processed food products and their containers must not come in direct contact with aluminum phosphide or with the spent aluminum phosphide product.

The Agency has given preliminary acceptance for aluminum phosphide as a restricted use rodenticide for the control of burrowing moles and rodents: Marmot sp. [woodchucks and yellow-belly marmot (rockchucks)], prairie dogs (except Utah prairie dogs), Norway and roof rats, ground squirrels, voles, house mice, gophers, and chipmunks. The products can only be used in noncrop areas and must not be applied within 15 feet of inhabited structures (i.e., the distance of linear diffusion for phosphine gas does not exceed 15 feet under this application condition) or to burrows which may open under or into occupied buildings. Aluminum phosphide is applied by adding 2 to 4 tablets (57% active ingredient) to the rodent burrow, packing the opening with crumpled newspaper and finally sealing the opening tightly by shoveling soil over the entrance. The newspaper prevents the soil from covering the tablets and slowing their action. The lower rate (2 tablets) is required for smaller burrows (e.g., rats, voles, ground squirrels, house mice, chipmunks) or under moist soil conditions, and the higher rate (4 tablets) for larger burrows (e.g., woodchucks, prairie dogs, gophers) or when the soil moisture is very low. Reopened burrows may be retreated 1 to 2 days after initial treatment. Because of the small amount of product used in this manner, the Agency does not expect the phosphine gas liberated from the aluminum phosphide product to remain in soil or water, or to remain in the vapor state for any measurable period of time such. Thus, an assessment of potential reentry hazard is not necessary for this use.

B. Environmental Fate Profile

The available data are insufficient to fully assess the environmental fate of aluminum phosphide or phosphine.

1. Microbiological - Effects of Pesticides on Microbes.

Ruschel and DaCosta (1966, MRID #005016261) treated "Rico 23" bean (*Phaseolus vulgaris L.*) seeds with aluminum phosphide by using three 3-g Phostoxin® tablets per cubic meter of defined area. Treated and control seeds were inoculated with a pure culture of *Rhizobium phaseoli* F33 (a nitrogen-fixing bacterium), sown in pots containing sandy soil (pH 4.5), and maintained under greenhouse conditions. The plants were sampled during the blooming period, and the following determinations for each plant were made: nodule number, dry weight, and percentage of nitrogen in the aboveground part of the plant. Phosphine had no apparent effect on nodulation (number of nodules) in bean plants grown from treated seed. However, the competency (i.e., ability to fix nitrogen) of the nodules was not reported.

2. Reentry

Childs *et al.* (1968?, MRID #000005691; 19??, MRID #000005735) reported phosphine gas concentrations in tobacco warehouses declined from 100-400 ppm to 1-5 ppm after aeration for 24 hours when fumigated with 3-g aluminum phosphide tablets (55% AlP) at 20 tablets/1,000 cubic feet. Phosphine gas concentrations were the same at the 1- and 14-foot sampling heights above the floor. Concentrations of phosphine gas in air within tobacco hogsheads declined from 100-400 ppm to ≤13 ppm after aeration for 48 hours. Warehouse temperature and relative humidity were monitored continuously at a central point in the building with a 7-day hygrothermograph located 4 feet above the floor next to the center aisle. In all warehouses the temperature ranged from 63° to 96°F (20° to 35°C) and the relative humidity from 47 to 63%. However, temperature and humidity effects on phosphine gas release and dissipation were not discernible from the data.

Levels of phosphine gas peaked at 1,200 ppm 3 days after application of aluminum phosphide (Phostoxin® at 165 pellets/1,000 cubic feet, purity unspecified) in a polyethylene-covered enclosure containing lined fiberboard cases of tobacco (Edmond *et al.*, 1971, MRID #000005737). Phosphine gas dissipated to nondetectable levels (<0.1 ppm) in air surrounding the cases 24 hours after removal of the cover even though the gas was present at 111-125 ppm inside the lined cases. Therefore, under warehouse conditions with aeration, the phosphine gas released from closed cases should be present at <0.1 ppm in the surrounding air.

Nelson (1970, MRID #000005797) found that phosphine concentrations in the air inside enclosed stacks of raisins peaked at 761 ppm and declined to 479 and 7 ppm within 6 and 50 days, respectively, after application of aluminum phosphide (purity unspecified) at 45 tablets/1,000 cubic feet. The rate of decline was not linearly related to the application rate. However, 99% of the phosphine gas inside enclosed stacks of raisins would be dissipated in the treated area 50 days after treatment without aeration. The level of phosphine gas in the treatment area with aeration was not determined for reentry.

Tuft (1960, MRID #000005664) detected phosphine gas in the air surrounding wheat* (approximately 200 pounds) treated with aluminum phosphide (Phostoxin®, 55% AlP) at 10 tablets per ton of wheat. The concentration in the air space around the wheat was 193 ppm one hour after treatment. This concentration had increased to a maximum level of 1,535 ppm at 56 hours after treatment and then decreased rapidly for about 150 hours without aeration. After 260 hours no phosphine was detected in the air surrounding the wheat. The level of phosphine gas in the treatment area with aeration was not determined for reentry.

Lauhoff Grain Company (1966, MRID #000005662) fumigated cornmeal in sealed boxcars with aluminum phosphide (Phostoxin®, 55% AlP) at a rate of 165 pellets/1,000 cubic feet. When whole pellets were used, phosphine gas levels 42-46 hours after fumigation ranged from <10 to 68 ppm (median 17 ppm)**. Data were extremely variable in boxcars treated with crushed or ground pellets, where phosphine gas concentrations ranged from <10 to 384 (median 26 ppm) 24 hours after fumigation. Therefore, the kinetics of phosphine release and dissipation cannot be generalized from these data.

In summary, phosphine gas generated from aluminum phosphide pellets and tablets is expected to decline rapidly in treated areas upon aeration. These levels of phosphine gas in the air surrounding the treated commodities should not be confused with the amount of residues in or on treated commodities (see Part VII, Residue Chemistry). Temperature and moisture also influence the release and dissipation of phosphine gas, however, data from these studies were insufficient to assess these factors. Therefore, reentry intervals and the kinetics of phosphine release and dissipation cannot be determined quantitatively from these studies.

C. Exposure Profile

Adequate data are not available to fully assess the potential for exposure of humans and wildlife to aluminum phosphide. Soil mobility data for assessing the groundwater contamination potential and bioaccumulation data are not available; however, the registered uses of aluminum phosphide are not expected to result in these types of exposure hazards. Exposure of wildlife (nontarget organisms) is unlikely to occur for the insecticide uses, given the use of aluminum phosphide as a fumigant for enclosed areas. However, the Agency is concerned about the fumigation of rodent burrows which may result in exposure hazards to endangered species (see Part VIII, Ecological Effects).

The greatest potential for direct exposure of humans is during handling, application, and reentry operations. Respiratory exposure is expected to be the main route of exposure because the toxic agent, phosphine, is a gas. Data for quantifying such exposures are lacking. Preliminary studies show that concentrations of phosphine gas released during fumigation with aluminum phosphide decline rapidly in treated areas upon aeration (Childs et al., 19??, MRID# 000005735; Childs et al., 1968?, MRID #000005691; Edmond et al., 1971, MRID #000005737; Nelson, 1970, MRID #000005797; Tuft, 1960, MRID #000005664; and Lauhoff Grain Company, 1966, MRID #000005662). However, inconsistencies in the data make it impossible to quantitate the duration, air volume, and method of aeration required to dissipate phosphine gas to safe levels in the application sites. After the Agency receives and evaluates the required reentry data for the insecticide use, the Agency may require that phosphide levels be monitored prior to reentering work areas*. Approved respirators by the U.S. Burea of Mines (designed for phosphine gas protection) should be worn by workers entering the fumigated areas until the phosphine gas dissipates to a safe level. The post-fumigation levels theoretically should decrease to some concentration approaching zero as the site is further aerated, but data is needed to determine the exposure levels, if any, to the applicator.

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* Air samples were removed at intervals (time) from a 60-gallon fiber drum containing common California red wheat through a glass tube inserted into the center of the drum, and approximately 2 feet below the surface of the grain.

** Samples of the gas were removed just before the boxcars were opened.

Dermal exposure may occur even when protective clothing is used because phosphine gas can penetrate a variety of materials, including polyethylene. Data for assessing such exposures are unavailable.

D. Summary of Data Gaps

The data gaps that are to be filled are hydrolysis, volatility and reentry. There are data gaps relating to disposal and storage, microbial metabolism (effects of pesticides on microbes) and activated sludge metabolism. However, pending review and modification of the testing protocols or a reassessment for the necessity for these data, it is currently not necessary to satisfy these data gaps.

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* Due to the lower volume of use (two or four tablets/burrow) and the use of the product away from inhabited areas, reentry data requirements will not be required for the rodenticide use.

VI. Toxicology

A. Introduction

Because of the highly toxic nature of phosphine and the ease with which it can be released from aluminum phosphide, the toxicity of aluminum phosphide has been assumed to be that of phosphine itself. Thus, the Agency has utilized the toxicological data on phosphine in regulating aluminum phosphide formulations and has not required the usual toxicological studies on aluminum phosphide or its formulations.

B. Application

The following discussion includes the application procedure which is required by the current labeling. The applicator, who must be certified, is required to notify the authorities such as the health departments, police departments and the fire departments so that any additional precautions may be taken, and emergencies may be handled promptly. The applicator should verify that the application site will properly contain the liberated phosphine and that the site is adequately secured against possible exposures to the surrounding areas. Posting warning signs and securing the areas with locks may be necessary to prevent workers from accidently entering a fumigated site.

After the aluminum phosphide is applied, concentrations of phosphine are allowed to build to the level (1,000 ppm may be necessary) needed for the fumigation process. The theoretical maximum concentration of phosphine in the air ranges from 1,500 to 3,000 ppm (pellets) and 1,500 to 11,000 ppm (tablets) which represents the highest possible level of exposure within the fumigation site. Field sampling methods may be used to verify the level achieved within the site (above 1,000 ppm). "High level" air sampling tubes which measure phosphine levels from 15 to 3,000 ppm are commercially available. When checking the levels of phosphine, the applicators are required to wear gas masks and canisters approved by the U.S. Bureau of Mines. Such gas masks are to be retained at the fumigation site in cases of emergencies requiring entry into the site.

The applicator or his designee are required to measure the areas surrounding an application site to verify that there is no leakage from the site into surrounding living or working areas. For this, the applicator may use "low level" sampling tubes which measure levels of phosphine in the range of 0.1 to 4 ppm.

After the fumigation process is completed, the applicator is required to aerate the site until phosphine levels are at or below 0.3 ppm so that the site may be opened and workers may safely enter the area. The applicator should verify that the aeration procedures do not discharge directly into areas in which humans may be working or living. The applicator, wearing protective clothing and a respirator, measures the air over and around the commodity which has been fumigated using low-level sampling tubes to insure that phosphine levels are at or below 0.3 ppm.

For the rodenticide use, the aluminum phosphide is applied by placing 2 to 4 tablets per burrow. The burrows are sealed tightly with soil over the entrance.

C. Toxicological Assessment

1. Acute Exposure Toxicity Summary

Table VI.A, Acute Inhalation Toxicity Summary for Phosphine, provides a comparison of different inhalation studies by descending chamber concentrations. Exposures generally lasted until animals started dying. Overall, the higher the concentration, the smaller the time interval to death. One study (Waritz and Brown, 1975, MRID #005007354) determined a LC_{50} concentration of 11 ppm or approximately 0.014 mg/liter. Although the study was classified as supplementary*, the LD_{50} derived from this study and information from the other studies cited in Table VI.A are sufficient to indicate that phosphine is highly toxic by the inhalation route, and for labeling purposes is in toxicity category I. Signs of toxicity resulting from acute exposure were primarily respiratory irritation and dyspnea (Waritz and Brown, 1975, MRID #005007354). The Agency requires no further acute toxicity studies using any route of administration (i.e., oral, dermal, inhalation, eye) for aluminum phosphide or phosphine.

2. Repeat Exposure Toxicity Summary

Table VI.B, Subchronic Inhalation Toxicity for Phosphine, summarizes the results of two major subchronic inhalation studies (Muller, 1940, MRID #GS0025022 and Klimmer, 1969, MRID #GS0025018). The results showed that as the exposure concentrations of phosphine decreased from 20 ppm to 5 ppm, the time interval to death generally increased. However, the increased time interval to death differed between the two studies.

Klimmer was able to maintain three species of animals without overt signs of toxicity for over 800 hours. The study was conducted over a six month period in which the test animals were exposure to phosphine at 2.5 ppm and 1 ppm for six hours/day for five days/week and four hours on Saturdays. At the next highest dose of 5 ppm, there were deaths in two of three species after approximately 30 hours. Thus, 2.5 ppm of phosphine can be considered as a no-observed-effect level (NOEL) for lethal effects and overt signs of toxicity during subchronic inhalation exposure.

Neither study would be judged adequate in evaluating all biological parameters deemed necessary by more modern toxicological requirements. Body weight changes, hematology, blood chemistry, organ weights, gross and histopathology evaluations were not performed in either study. Numbers of animals per dose were usually too low. Nevertheless, the studies do provide a good estimate of the dose-response relationship for the toxic effects of phosphine with different species.

Until the results of reentry data are received and evaluated concerning exposure to phosphine from registered uses of aluminum phosphide, the Agency will not request additional subchronic inhalation studies at this time.

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* This study is considered supplementary because only one sex was tested and complete details concerning all test parameters were not provided.

TABLE VI.A

Acute Inhalation Toxicity Study Summary for Phosphine

Concentration (ppm)	Exposure	Species	Time to Death	Citations
60,000–70,000	Continuous	Frog	3 hours	Brilliant, 1832[a]
2,500	25 minutes	Cat	51 minutes	Brilliant, 1832[a]
2,000	Continuous	Rabbit	33 minutes	Henderson & Bubois, 1879[a]
1,500	10 minutes	Rabbit	10 minutes	Meissner, 1924[a]
600	Continuous	Rat	1 hour	Rebmann, 1933[a]
540	Continuous	Mouse	35 minutes	Jakote, 1904[a]
403	46 minutes	Rat	36 minutes	Klimmer, 1969
400	30 minutes	Rabbit	50 minutes	Jakote, 1909[a]
300	Continuous	Guinea pig	2 hours	Rebmann, 1933[a]
205	75 minutes	Rat	66 minutes	Klimmer, 1969
167	100 minutes	Cat	93 minutes	Klimmer, 1969
167	100 minutes	Rabbit	90–98 minutes	Klimmer, 1969
167	100 minutes	Rat	70–75 minutes	Klimmer, 1969
160	Continuous	Hen	50–64 minutes	Klimmer, 1969
151	Continuous	Turkey	68, 74, 80 minutes	Klimmer, 1969
150	Continuous	Cat	160 minutes	Jakote, 1904[a]
140	110 minutes	Rat	97 minutes	Klimmer, 1969
120	130 minutes	Cat	103–130 minutes	Klimmer, 1969
120	130 minutes	Rabbit	110–125 minutes	Klimmer, 1969
120	130 minutes	Rat	79–123 minutes	Klimmer, 1969
60	Continuous	Rat	4 hours	Rebmann, 1933[a]
54	6.5 hours	Cat	5–6.5 hours	Klimmer, 1969
54	6.5 hours	Guinea pig	4–5.5 hours	Klimmer, 1969
54	6.5 hours	Rat	4–5.5 hours	Klimmer, 1969
50	150 minutes	Cat	4–5 hours	Jakote, 1904[a]
42–50	Continuous	Rat	5–7 hours	Muthu, 1980
25	4 hours	Guinea pig	4 hours	Muller, 1940
25	4 hours	Rabbit	4 hours	Muller, 1940
25	8.5 hours	Cat	8.5 hours	Klimmer, 1969
25	8.5 hours	Rabbit	5–8.5 hours	Klimmer, 1969
25	8.5 hours	Rat	7–8 hours	Klimmer, 1969
11 (0.014 mg/l)	4 hours	Rat	LC_{50}	Waritz & Brown, 1975

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a. Parkin, 1972.

Table VI.B

Subchronic Inhalation Toxicity Summary for Phosphine

Concentration (ppm)	Exposure [hr/day (hr) x days (d)]	Species	Time to death [hours (hr) or days (d)]	Reference
20	4 hr x 2 d	Rabbit	2 d	Muller, 1940
20	4 hr x 2 d	Guinea pig	2 d	Muller, 1940
14.8 and	4 hr x 6 d	Rabbit	6 d	Muller, 1940
10	4 hr x 7-14 d	Rabbit	7-15 d	Muller, 1940
8.3	4 hr x 4-5 d	Rabbit	4, 6 d	Muller, 1940
8.3	4 hr x 47 d	Rabbit	-	Muller, 1940
5	4 hr x 6 d	Rabbit	6 d	Muller, 1940
5	48 hr	Cat	35.5-45.5 hr	Klimmer, 1969
	(continuous)	Guinea pig	24-32 hr	Klimmer, 1969
		Rat	27-36 hr	Klimmer, 1969
5	80 hr	Guinea pig	30 hr	Klimmer, 1969
	(continuous)	Rat	32-48 hr	Klimmer, 1969
		Cat (2)	-	Klimmer, 1969
		Rat (2)	-	Klimmer, 1969
2.5	820 hr[a]	Cat	0/4[b]	Klimmer, 1969
		Guinea pig	0/4[b]	Klimmer, 1969
		Rat	0/10[b]	Klimmer, 1969
1	816 hr[a]	Cat	0/4[b]	Klimmer, 1969
		Rat	0/10[b]	Klimmer, 1969

a. Six hr/day, 5 day/wk, 4 hr on Saturdays.

b. Zero deaths out of four (or ten) treated animals.

D. Human Poisoning Case Reports

The Agency's Pesticide Incident Monitoring System (1981) reported 29 incidents involving human pesticide exposure from aluminum phosphide. These incidents occurred from 1966 to March, 1981 and involved an estimated 80 to 90 people. Seventy-one of the exposed persons received medical treatment while an additional 33 persons were hospitalized, with a total of 2 fatalities.

In 22 incidents, pesticide exposure occurred when aluminum phosphide was used as a grain fumigant. Truck drivers, pesticide applicators, railroad, warehouse and mill workers, laborers and cargo crew members constituted the majority of personnel exposed in this manner. Two home-related incidents, involving 9 children under the age of 16 (one of which died) and one adult, were also reported. These two home-related incidents were clearly a misuse since the user disregarded the label instructions. The other incidents were attributed to accidental pesticide spills or were of undetermined origin. In all of these incidents, exposure to aluminum phosphide or phosphine occurred through improper handling of the pesticide (not wearing required protective clothing), incomplete aeration procedures (i.e., not determining phosphine levels prior to reentry or not wearing the required respirator), or improper rates of application of the pesticide to the commodities.

In the literature, 12 studies dating from 1936 to 1980, reported case histories of human exposure to phosphine gas. A total of 129 persons were exposed to the gas in varying situations. These studies have described gastrointestinal disorders which included vomiting and diarrhea, and nausea as the most prevalent symptoms. Headache, dizziness and breathing difficulties were also noted. In the survivors, recovery times ranged from 24 hours to 1 month following exposure. Autopsy findings indicated that pulmonary edema and congestive heart failure were the most frequent causes of death from phosphine gas exposure.

One of these studies (Zipf et al., 1967, MRID #005017653) which addressed a suicide attempt with Phostoxin® provided a description of medical treatment following aluminum phosphide poisoning. The authors recommended a rapid and thorough stomach evacuation irrigation, irrigation with 1% potassium permanganate solution or magnesium peroxide and treatment with activated charcoal and sodium sulfate. Thereafter, immediate administration of oxygen, they indicated, will help to prevent death from circulatory system collapse and pulmonary edema. When renal insufficiency is present, extracorporeal hemodialysis proved effective.

E. Permissible Exposure Limits

The American Conference of Industrial Hygienists (ACIH, 1971) has established a normal allowable occupational exposure limit (TLV) of 0.3 ppm for phosphine based on acute and subchronic inhalation studies. This has also been adopted by National Institute of Occupational Safety and Health (NIOSH, 1979) and Occupational Safety and Health Administration (NIOSH/OSHA, 1978) as a permissible exposure limit (PEL). Both the TLV and the PEL represent time weighted averages of airborne concentrations which should not cause harm to workers exposed eight hours per day, five days per week throughout a working lifetime.

Because the Agency is concerned about adverse chronic effects, other than overt symptoms and lethality, we reserve the decision to require some studies, such as mutagenicity and teratology, until the results of reentry data can be evaluated. If there is significant chronic exposure to the applicator based on this review, the Agency may require these studies.

F. Food Tolerances

Considering that phosphine is a gas and thus only low levels of phosphine residues are expected in treated food commodities, it is anticipated that the public which consumes phosphine-treated food commodities will be exposed to toxicologically insignificant quantities of phosphine per se (see Part VII, Residue Chemistry). As no significant dietary exposure to phosphine is expected, no chronic feeding, oncogenic, metabolism or reproduction studies are required for phosphine.

However, chemically uncharacterized residues are found in food commodities as a result of phosphine treatment (see Part VII, Residue Chemistry). There is a chronic feeding/oncogenic study (Hackenberg, 1969, MRID #000026937; 1971, MRID #000026938; 1972, MRID #000006000) in which rats were fed a phosphine-treated diet and were presumably exposed to levels of chemically uncharacterized residues which result from phosphine treatment. The Hackenberg study is an inadequate measure of the possible hazards arising from the consumption of these residues. The levels of this chemically uncharacterized substance are unknown and are very likely below the maximum tolerated dose. Therefore, the study, at best, is very insensitive. Nevertheless, it provides no evidence that any harm will result from consumption of phosphine-treated food commodities. It is therefore reasonable to defer the requirement for chronic feeding, oncogenic, metabolism and reproduction studies pending a determination of the chemical nature of the chemically uncharacterized residues.

If the Agency concludes, when these residues are chemically characterized, that they are toxicologically insignificant, the requirement for chronic feeding, oncogenic, metabolism, and reproduction studies will be waived. If no determination can be made, chronic feeding, oncogenic, metabolism, and reproduction studies may be required. Therefore, the requirement for these studies is being deferred until the residues are chemically characterized, and the Agency reviews the results.

G. Summary of Data Gaps

All required toxicology studies are reserved pending the receipt and evalution of residue and reentry data. When the chemically uncharacterized residues which result from the treatment of food commodities with phosphine are characterized and evaluated, the Agency will determine whether chronic feeding/oncogenic, metabolism and reproduction studies are required. When the reentry data are received and evaluated to determine if there is any exposure to the applicator, the Agency will determine whether mutagenicity, teratology and additional subchronic inhalation studies are required.

VII. Residue Chemistry

A. Introduction

Aluminum phosphide (AlP) is used for the control of insects in raw agricultural commodities, processed foods, and animal feeds. Two types of fumigation treatments are recommended. To fumigate grain that is unbagged and stored in bulk (i.e., grain elevators, rail cars, and bins), the registered aluminum phosphide product (i.e., pellets, tablets) is blended with the commodity either manually or with a special applicator to assure uniform blending. The other procedure is to fumigate grain that has been bagged, processed foods and feeds, and miscellaneous commodities (e.g., tobacco) by placing the product in moisture-permeable envelopes and/or cardboard trays. In this procedure, aluminum phosphide cannot be mixed directly with these commodities*. Because the application process for aluminum phosphide determines the amount of residues which might remain in the treated commodity, appropriate application rates must be used to assure that phosphine do not exceed the established tolerances. A detailed use pattern concerning application rates, sites, pests, and limitations that the Agency has accepted for end-use products containing aluminum phosphide as the sole active ingredient can be found in the Agency's Registration Standard Chemical Aluminum Phosphide Index Entry (EPA, 1931) and is summarized below:

1. Raw Agricultural Commodities (e.g., wheat)

When blended with unbagged grains stored in bulk, the accepted application rates are from 2.7 to 10.3 grams of aluminum phosphide per short ton of grain, and from 40 to 308 grams of aluminum phosphide per 1,000 bushels of grain (wheat), depending on the conditions of fumigation.

2. Raw Agricultural Commodities (other than wheat, etc.), Processed Food, and Feed

When the aluminum phosphide is not directly blended with the commodity, the accepted application rates range from 34 to 206 grams of aluminum phosphide per 1,000 cubic feet of space.

3. Miscellaneous Applications

a. Tobacco: The accepted rates range from 33 to 248 grams of aluminum phosphide per 1,000 cubic feet of space.

b. Empty Beehives: The accepted rates range from 49.5 to 74.3 grams of aluminum phosphide per 1,000 cubic feet of space.

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* Except for making beer, aluminum phosphide is prohibited from being blended directly with processed foods and feeds since small amounts of unreacted aluminum phosphide may collect in the treated commodities. In raw agricultural commodities, the Agency assumes that these small amounts of unreacted aluminum phosphide residue are eliminated by continued exposure to atmospheric moisture, by processing, and by cooking.

c. Stored Nonfood/Nonfeed Products (e.g., cotton (cloth and/or processed), feathers, seed): The accepted rates range from 3.3 grams to 10 grams of aluminum phosphide per ton and from 58 grams to 116.3 grams of aluminum phosphide per 1,000 cubic feet of space.

d. Commercial Establishments (e.g., cereal mills): To fumigate commodities stored in these areas, the acceptable rates range from 33 to 50 grams of aluminum phosphide per 1,000 cubic feet of space.

Many of the submissions supporting the registration of aluminum phosphide products are based on laboratory studies conducted with phosphine rather than aluminum phosphide. To relate the two systems, the following table can be used:

Aluminum Phosphide (1.000 ppm)	Equivalent Phosphine (0.587 gm)
Mixed with Commodity:	
10.0 grams/ton grain (wheat)	6.5 microgram/gram (wheat)
0.30 grams/bushel (ca 60 lb, wheat)	6.5 microgram/gram (wheat)
300.0 grams/1,000 bushel (wheat)	6.5 microgram/gram (wheat)
	10.5 milligram/liter of fumigated volume (i.e., air space within the wheat)
Separated from commodity:	
200.0 grams/1,000 cubic feet	4.15 mg/liter (1.20 gm 70°F)*
	3450 ppm by weight
	2960 ppm by volume (Specific Gravity 1.17)**
7.06 grams/cubic meter	4.15 mg/liter

When the aluminum phosphide product and commodity are blended, the exposure times vary, depending upon the pest, and the nature and temperature of the commodity. When the product and commodity are not blended, the exposure times are dependent on the nature of the commodity and the temperature of the storage space. For commodities blended with aluminum phosphide, fumigation times range from 2 days for wheat at temperatures of 68°F (20°C) and above, to 14 days for wheat at 40°F (4.4°C). For commodities not blended with aluminum phosphide, the recommended exposure temperature is 68°F (20°C) and the fumigation time is 6 days.

B. Residues Following Aeration

For all commodities treated with aluminum phosphide, except for tobacco, an aeration time of at least 2 days (48 hours) is required. For tobacco, the minimum aeration time is two days except when the fumigated tobacco is in hogsheads, in which case the minimum time is 72 hours. The following three studies show that residues of phosphine decline rapidly with aeration, that is, the phosphine simply diffuses from the fumigated commodity into the ambient air. Data are included for raw agricultural commodities, processed foods, and feeds.

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* Weight of one liter of air at 70°F (21.1°C) and 760 mm.

** Calculated by taking the specific gravity of air equal to 1.00 and the specific gravity of phosphine, 1.17.

In one study (Hild and Mayer, 1965, MRID #00020578), the decline of phosphine residue was rapid from a variety of foodstuffs [almonds, barley, beans (white), bran (wheat), cocoa (oil-free), flour (wheat and potato), hazelnut kernels, lentils, peas (green), rice, semolina, sugar, sultanas, and noodles]. In this study, the foodstuffs were fumigated under a polyethylene tarpaulin for 72 hours at a rate equivalent to 5 grams of aluminum phosphide per cubic meter. The area surrounding the stacked commodities was monitored for phosphine. After 2 hours of aeration, the maximum residues of phosphine ranged from 0.7 ppm in wheat to 3.25 ppm in lentils; after 24 hours, from 0.05 ppm in sugar lumps to 0.45 ppm in rice. After 48 hours, residues of phosphine were not detectable in any of the fumigated commodities.

In a second study (Sullivan *et al*., 1969. MRID #000022017), the phosphine residues were determined in samples of whole nuts (raw almonds, raw walnuts, and raw and roasted peanuts) after application of Phostoxin® pellets at rates equivalent to 10 grams of aluminum phosphide per 1,000 cubic feet. After 48 hours of aeration, residues in these samples did not exceed 0.1 ppm; at zero hours the maximum residues ranged from 3.8 ppm (raw peanuts) to 8.3 ppm (roasted peanuts); at 24 hours, from 0.21 ppm (almonds) to 0.47 ppm (roasted peanuts); at 48 hours, from 0.030 ppm (walnuts) to 0.042 ppm (roasted peanuts).

Sullivan (1969, MRID #000005636) showed that residues of phosphine in fumigated tobacco declined rapidly to acceptable levels (i.e., less than 0.1 ppm, see the Special Chemistry Requirements, 43 FR Section 163.64-1, July 10, 1978, "Proposed Guidelines"). When treating flue-cured tobacco at the recommended rate of 30 pellets of Phostoxin® (*ca*. 10 grams of aluminum phosphide) per 1,000 cubic feet of space for a period of 96 hours, the maximum residue of phosphine at zero hours was 4.2 ppm; after 24 hours, 0.093 ppm; after 48 hours, 0.026 ppm; after 72 hours, 0.010 ppm. These phosphine residues were determined by a variation of the method of Bruce *et al*. (1962, MRID #005007190).

C. Metabolism in Plants and Animals

Data to establish the identity of metabolites of phosphine *per se*, which might be sorbed as minute residues on ingested animal feeds, have not been submitted to the Agency, nor have data been found in the scientific literature to show the metabolites of phosphine by plants. The reviewed studies show, however, that after thorough aeration of the phosphine, neither the germination of grain nor its baking qualities as flour (Freyman and Sosedov, 1957, MRID #005018681), nor its vitamin content (Dieterich *et al*., 1967, MRID #005008303) were changed by phosphine fumigation.

The nature of the residue resulting from the accepted uses of aluminum phosphide as a source of phosphine for fumigating raw agricultural commodities and processed foods and feeds is not well established. Phosphine is slowly released by a reaction of aluminum phosphide with atmospheric moisture. To slow the reaction and the rate of release of phosphine, the formulated tablets and pellets of aluminum phosphide are often coated. The nonvolatile residues of these products consist of the coating material, oxides of aluminum and small amounts of unreacted aluminum phosphide. Such nonvolatile residues can occur only when aluminum phosphide is blended with a raw agricultural commodity.

Because the required labeling prohibits contact of processed foods and feeds with the aluminum phosphide product, the resulting residues in such commodities would be limited to phosphine, which might be sorbed, and the reaction product(s) of phosphine with such commodities.

The initial studies establishing the phosphine tolerances in and on grain were limited to chemical procedures and these studies contained little or no evidence that phosphine reacted chemically with the treated commodities. However, since 1972, fumigation studies conducted with $^{32}PH_3$ (Tkachuk, 1977, MRID #005008840; Disney and Fowler, 1972, MRID #005015384; and Robinson and Bond, 1970, MRID #005013027) have shown that residues resulting from fumigation with phosphine are not limited to phosphine and that the phosphine also reacts irreversibly with constituent(s) of wheat, oilseeds, and probably other fumigated commodities. A nuclear activation study (Robinson, 1972, MRID #005007621) supports the results of these radiolabeled studies and indicates the reported residues were due neither to an exchange of ^{32}P with ^{31}P nor to an enhanced chemical activity of $^{32}PH_3$ over PH_3. These studies also show that for phosphine, the rates both for sorption (physical) and reaction (chemical) with treated commodities are dependent upon the conditions of fumigation (e.g., temperature, humidity and moisture in the commodity, fumigation time, and concentration of phosphine in the fumigated space).

Tkachuk (1977, MRID #005008840) showed that phosphine reacting with wheat and flax during a five-day fumigation period was 37% and 45%, respectively, of total phosphine applied. These residues resulted from fumigation rates approximately 2.2 times the recommended rate of 10 gm/ton (about 6.5 micrograms PH_3/gram of wheat). In both instances, the phosphine reaction products with the grain were in excess of 5 ppm. Smaller amounts of similar residues were found in fumigated wheat flour and in bread baked from such flour. In these and other ^{32}P-studies, the phosphine reaction products with wheat were shown to consist of the oxy-acids of phosphorus (phosphoric, phosphorous, and hypophosphorous) and a residue(s) that was approximately 30% of the total ^{32}P residue in the wheat, which was not identified. Based on the data of this study, unidentified residue in wheat following the maximum recommended application rate (10 gram aluminum phosphide/ton) would be about 0.7 ppm [viz., 37% of applied phosphine (ca 6.5 ppm) reacts chemically with the wheat or about 2.4 ppm; 30% of the residue resulting from the reaction has not been identified]. It is presumed that unidentified residue(s) in the Tkachuk study was not sorbed phosphine. However, one recent study (Dumas, 1930, MRID #005020467) indicated that small amounts of unexplained phosphine (in parts per trillion) were still being released from a large quantity of unbagged wheat after aerating for 120 days.

D. Analytical Methods

Since 1962, the method of Bruce et al. (1962, MRID #005007190) has been available as an acceptable procedure for determining residues of phosphine in grains. In this procedure, a sample of fumigated grain is treated with dilute sulfuric acid in an aeration apparatus that consists, essentially, of a five liter flask attached to two "gas scrubbers" containing bromine water. Nitrogen is bubbled through the apparatus for 30 minutes at room temperature and then for an additional 2 hours at the boiling temperature. Any aluminum phosphide that may be present as a residue would be hydrolyzed to phosphine in this step. After two hours of boiling, the bromine water gas-scrubbers are detached and the bromine water (containing phosphine oxidized with bromine to phosphate) concentrated to remove bromine. The concentrated solution is then diluted to a standard volume and aliquots are taken for a colorimetric determination of phosphate by the method of Fisk and Subbarow (1925).

With the exception of a few erratic results, good recoveries for phosphine, averaging 90% for wheat, were reported in the original paper. However, recovery studies on a variety of commodities by other investigators have given somewhat erratic results. At least in part, the erratic results are explained by several recent studies conducted with ^{32}P-phosphine showing that some of the fumigating phosphine reacts irreversibly with one or more of the constituents present in wheat, oilseeds, and other commodities (see previous discussion under Metabolism in Plants and Animals, Section E).

The Bruce et al. method (1962, MRID #005007190) is generally accepted for determining residues of phosphine in both agricultural commodities and processed foods and has been adapted for use as an enforcement method [see Pesticide Analytical Manual (PAM), 1980, Vol. II]. Although Bruce et al. (1962, MRID #005007190) estimated the sensitivity of the method at about 0.005 ppm, the adapted procedure in PAM, Vol. II, estimates the sensitivity at 0.01 ppm.

E. Residue Data

For aluminum phosphide, the residue of toxiological interest for which tolerances have been established is phosphine; supporting residue data have been submitted for the following types of applications: 1) stored grains, 2) raw agricultural commodities (processed foods and feeds), and 3) miscellaneous applications.

1. Raw Agricultural Commodites (e.g., wheat)

When the Agency first reviewed aluminum phosphide for use as a treatment for unbagged grain, the aluminum phosphide was blended with the grain. Supporting this use was a study by Bruce et al. (1962, MRID #005007190) reporting the results from 16 laboratory tests and field trials for residues of phosphine in or on wheat and corn.

The reported laboratory data reflect application of aluminum phosphide mixed with the grain at the maximum rate of 10 grams per ton. The field data reported are for wheat stored in bins and treated at the recommended rate. Based on both the laboratory and field data, residues of phosphine after two days of fumigation in whole grains, wheat, and corn, were less than 0.1 ppm. The maximum residue reported in the field studies was 0.046 ppm and the sensitivity claimed for the method was 0.005 ppm.

The following four studies are typical of the residues of phosphine obtained by mixing aluminum phosphide with other raw agricultural commodities:

Sullivan (1972, MRID #000006742) determined the residues of phosphine in the grain after applications under typical field conditions of 300 pellets of Phostoxin® per 1,000 bushels (bu) of grain [5,000 bu corn; 3,500 bu wheat; 6,000 bu milo; and 3,100 bu rye], a rate which is equivalent to about 100 grams aluminum phosphide/1,000 bushels. Using the procedure of Bruce et al. (1962, MRID #005007190), the residues of phosphine were less than 0.004 ppm.

Vardell et al. (1973, MRID #005013439) determined phosphine residues on soybeans that were fumigated for periods of two to five days. They used pellets (approximately 0.60 gram) of aluminum phosphide (about 55% active ingredient) and steel drums of varying size. The highest application rate was 5.1 pellets (about 1.7 grams phosphine) per cubic meter. The residues of phosphine following 24 hours of aeration did not exceed 0.002 ppm, except for one aberrant value of 0.04 ppm.

Guvener et al. (1970, MRID #005016260) determined phosphine residues in barley and rye following an application of aluminum phosphide at the maximum rate (10 gm/ton) and aeration for 3 days. The phosphine residue in barley ranged from 0.04 to 0.62 ppm and in rye from 0.09 to 0.12 ppm.

Kavadia et al. (1979, MRID #005022032) sampled wheat and maize fumigated for 3 days in airtight drums following applications of aluminum phosphide at the rate of 1 to 4 tablets per ton (1 to 4 grams/ton). The maximum phosphine residue reported in this study was 0.031 ppm.

A few studies report exceptionally high residues of phosphine in commodities treated by direct mixing with the aluminum phosphide, one of which is reported by Panetsos and Kilikidis (1973, MRID #005013276). Following an application of aluminum phosphide at a rate of 0.55 gm/10 kg of wheat, the fumigated wheat was aerated in an open vessel (depth of the wheat was less than 10 cm). The phosphine residues in the aerating wheat were determined daily for 12 days. The residues declined steadily from 83 ppm after 24 hours to 0.3 ppm after 12 days. The higher residues found in this study are explained by the presence of unhydrolyzed aluminum phosphide in the samples taken for analysis. Such nonvolatile residues also partially explain the higher (>0.1 ppm) aberrant residues reported for phosphine in raw grains and the typically lower residues (<0.01 ppm) found in flour and other processed foods that are not mixed with aluminum phosphide.

2. Raw Agricultural Commodities (other than wheat, etc.), Processed Foods and Feeds

The unreacted residues of aluminum phosphide may cause significant residue of phosphine in treated commodities. For this reason, aluminum phosphide is not directly mixed with foods, feeds, and raw agricultural products that may be used directly as food. In order to avoid the possibility of such contamination, the following label warning is commonly required: "Under no condition shall any processed food come in contact with aluminum phosphide or aluminum phosphide residues." Several studies reported residues of phosphine for a variety of commodities which were fumigated without mixing with aluminum phosphide.

Recently, Rosebrook (1972, MRID #000005750) reported valid residue data for a variety of commodities, including bagged grains, treated at a rate of either 58 or 580 grams of aluminum phosphide (3 or 30 bags of Detia Gas Ex-B (57%), net weight 34 grams) in a 1,000 cubic foot fumigation chamber. These fumigations were equal to 0.5X (times) and 5X the maximum recommended rate of 6 Detia bags of product per 1,000 cubic feet. In this study, the period of fumigation was five days.

In addition to grains, this study (Rosebrook, 1972, MRID #000005750) includes phosphine residue data for the following raw agricultural commodities for which aluminum phosphide has been accepted as a fumigating agent: barley, beans (raw cocoa and coffee), corn, dates, peanuts, soybeans and other seed and pod vegetables, nuts, whole spice, and cottonseed. Phosphine residue data were also included for specific items in the following categories of processed commodities: animal feeds (dried); coffee, cocoa and tea; cookies, crackers, and snacks; candy, sugar and gelatin; milk and milk products (dried); fruit, vegetables, eggs, etc. (dried); flour, and other grain by-products; herbs, spices, and seasonings; meat, fish, and cheese; and nuts, packaged cereals and pastry mixes. After 48 hours of aeration, accomplished by blowing air into the chamber with a box fan at an unspecified rate, residues of phosphine in products treated with aluminum phosphide at the lower 0.5X rate were generally less than 0.01 ppm; at the higher 5X rate, less than 0.1 ppm. The highest aberrant residue data following application at the 0.5X rate were reported in wheat bran (0.034 ppm); at the 5X rate, in roasted coffee beans (0.370 ppm). These residues were determined by a Drager Tube method. The results by this procedure were shown not to differ significantly from results obtained with the procedure by Bruce et al. (1962, MRID #005007190). With minor exceptions, these residues declined on continued aeration to less than 0.1 ppm.

The following studies show the amount of the phosphine residues detected in commodities that were fumigated without mixing the commodity with aluminum phosphide.

Sullivan (1966, MRID #000005775) reported residues of phosphine for 49 processed foods (including flour, dried fruit, nuts, and animal feed) treated at the recommended rate of 165 pellets (55 grams) of aluminum phosphide per 1,000 cubic feet. The reported residues were <0.004 ppm.

Sullivan and Starr (1966, MRID #000022007) reported residues of phosphine for eight varieties of processed fruit that were treated with aluminum phosphide at exaggerated rates of 3X, 31X, and 68X above the recommended rate. The recommended rate being 165 pellets (55 gms) of aluminum phosphide per 1,000 cubic feet. The highest residue (<0.1 ppm) was reported for dried apples treated at the 68X rate.

Sullivan and Wooldridge (1966, MRID #000022026) fumigated five processed foods at the recommended rate with Phostoxin® tablets (165 pellets per 1,000 cubic feet). With the exception of dried apples (0.015 ppm) the reported residues were <0.003 ppm.

3. Miscellaneous Applications

In a study previously discussed, Rosebrook (1972, MRID #000005750) also fumigated cigarette and cigar tobacco products. The residues reported were less than 0.1 ppm.

4. Residues in Meat, Milk, Poultry and Eggs

The data upon which this Standard is based does not include data on the carry-over of residues of phosphine to meat, milk, poultry, and eggs. The carryover of aluminum phosphide would not be expected because it reacts very readily with moisture, including moisture in the feed, to form phosphine. To prevent contamination, the aluminum phosphide product must not come into contact with these commodities. This restriction is currently stated on all registered aluminum phosphide end-use products.

F. Summary of Data Gaps

As discussed in Section C, Metabolism by Plants and Animals, phosphine reacts irreversibly with treated commodities. Grain fumigation studies conducted with ^{32}P-phosphine indicate these irreversibly bound residues consisted of both the oxy-acids of phosphorous ($\leq$2.5 ppm) and unidentified residues (ca 0.7 ppm). These studies also indicated that the same or similar residues, in about the same quantities, are present in all commodities fumigated with phosphine. Thus, in order to evaluate the hazards that would be associated with the use of the pesticide, the Agency is requiring that these unidentified residues be either identified chemically and recognized as safe, or tested in accordance with the Agency's Guidelines.

VIII. Ecological Effects

Subpart E, Hazard Evaluation: "Wildlife and Aquatic Organisms," of the Proposed Guidelines issued on July 10, 1978, describes the fish and wildlife data requirements needed by the Agency to assess the hazards of pesticides to nontarget organisms and to provide for adequate precautionary labeling. There are no fish and wildlife toxicity studies on aluminum phosphide. However, such data will not be required to support the use patterns covered by this standard because 1) aluminum phosphide, in the presence of moisture, decomposes rapidly to produce phosphine gas; 2) the treatment sites for the insecticide use are enclosed or covered during treatment, thereby precluding exposure to fish and wildlife; and 3) the residual phosphine will be diluted upon release into the surrounding air when venting a treated area. Thus, the Agency will waive the ecological effects data requirements regarding the currently registered uses (i.e., the fumigation of foods, feeds, processed foods and feeds in enclosed structures, and the fumigation of rodent burrows) for aluminum phosphide products.

The use patterns of aluminum phosphide for controlling burrowing rodents and moles could destroy nontarget mammalian, avian, and reptilian species that prey on these pests or are utilizing their burrows at the time of application. The following endangered species were determined to be in jeopardy through the use of this product*: 1) Black-footed ferret (*Mustela nigripes*); 2) Eastern indigo snake (*Drymarchon corais cauperi*); 3) San Joaquin kit fox (*Vulpes macrotis mutica*); 4) Utah prairie dogs (*Cynomys parvidens*); 5) Blunt-nosed leopard lizard (*Gamelia*: *Crotaphytus*); and 6) Desert tortoise (*Gopherus agassizii*). The Agency will require labeling changes for products covered by this Standard to reduce and/or eliminate potential hazards to nontarget organisms; i.e., endangered species (see Part II).

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* These species were determined through formal Section 7 consultation with the Office of Endangered Species, U.S. Fish and Wildlife Service.

IX. Confidential Annex

Persons wishing to read the contents of this annex, which contains Confidential Business Information, are requested to contact the United States Environmental Protection Agency, Office of Pesticide Programs, Information Services Branch (Freedom of Information), for further details.

X. Bibliography

A. Guide to Use of This Bibliography

1. Content of Bibliography

This bibliography contains citations of all the studies reviewed by EPA in arriving at the positions and conclusions stated elsewhere in this Standard. The bibliography is divided into 3 sections: 1) citations that contributed information useful to the review of the chemical and considered to be part of the data base supporting registrations under the Standard; 2) citations examined and judged to be inappropriate for use in developing the Standard; and 3) standard reference material. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions, and the published technical literature.

2. Units of Entry

The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to a published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries on them, treating them as a single study.

3. Identification of Entries

The entries in this bibliography are sorted by author, date of the document, and title. Each entry bears, to the left of the citation proper, a nine-digit identifier. This number is unique to the citation, and should be used at any time specific reference is required. This number is called the "Master Record Identifier," or "MRID." It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted data (see paragraph 4(d)(4) below for further explanation).

4. Form of the Entry

In addition to the Master Record Identifier (MRID), each entry consists of a bibliographic citation containing standard elements followed, in the case of materials submitted to EPA, by description of the earliest known submission. The bibliographic conventions used reflect the standards for the American National Standards Institute (ANSI) and was expanded to provide for certain special needs. Some explanatory notes of specific elements follow:

a. Author

Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first known submitter as author.

b. Document Date

When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title

This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between brackets.

d. Trailing Parentheses

This is the third element in the citation. In some cases it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between brackets.

e. Trailing Parentheses

For studies submitted to us in the past, the following elements describing the earliest known submission (in addition to any self-explanatory text) are included within the trailing parentheses.

1) Submission Date. Immediately following the word "received" appears the date of the earliest known submission.

2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental permit number, petition number, or other administrative number associated with the earliest known submission.

3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

4) Volume Identification. The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library". This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th,123456-Z and the 27th 123456-AA.

ALUMINUM PHOSPHIDE BIBLIOGRAPHY

Section 1

Citations Considered To Be Part Of The Data Base Supporting Registration Under The Standard

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

Product Chemistry (Part IV)

MRID #	Citation
005007818	Bond, E.J.; Dumas, T. (1967) Loss of warning odour from phosphine. Journal of Stored Products Research 3:389-392.
000005672	Codex Committee on Pesticide Residues (1966) Working Paper on Residue Tolerances of Hydrogen phosphide as Derived from Aluminium phosphide in Grain and Grain Products. (CCPR.66.13; First Session Jan 17-22, 1966, The Hague, The Netherlands; unpublished study received on unknown date under 5857-1; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:121108-A)
000005761	DEGESCH America, Incorporated (1944?) Method of Analysis for Phostoxin and Phostoxin Treated Grain: Determination of Aluminium phosphide (as phosphine) and Ammonium carbamate (as Carbon dioxide and Ammonia) in Phostoxin. (Unpublished study received Aug 9, 1977 under 40285-3; CDL:231203-D)
000005762	DEGESCH America, Incorporated (1977) Chemistry Data: [Phostoxin]. (Unpublished study received Aug 9, 1977 under 40285-2; CDL: 231205-A)
000005760	DEGESCH America, Incorporated (1977) Report on Phostoxin (R)* New Coated Tablets Storage/Shelf Life Stability Study. (Unpublished study including letter dated Jun 20, 1977 from H. Kelm to Whom It May Concern, received Aug 9, 1977 under 40285-1; prepared in cooperation with Univ. Frankfurt, Institut fuer physikalische Chemie; CDL:231204-B)
000005759	DEGESCH America, Incorporated (1977) Report on Phostoxin (R)* Pellets Storage/Shelf Life Stability Study. (Unpublished study including letter dated Jul 15, 1977 from H. Kelm to Whom It May Concern, received Aug 9, 1977 under 40285-3; prepared in cooperation with Univ. Frankfurt, Institut fuer physikalische Chemie; CDL:231203-B)
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Citations Considered to be Part of the Data Base Supporting Registrations Under the Standard

Product Chemistry (Part IV) (Cont'd)

MRID #	Citation
000005681	Dufour, R.E. (1961) Report on Fumigant: MH7330. Includes six methods dated Apr 12, 1961. (Unpublished study received Jun 12, 1961 under 5857-1; prepared by Underwriters' Laboratories, Inc. for Hollywood Termite Control Co., Inc., submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:022509-A)
000005813	Fluck, E. (1973) The Fate of Phosphine in the Atmosphere. (Unpublished study received Apr 27, 1976 under 5857-5; prepared by Univ. Stuttgart, Institut fuer Anorganische Chemie; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:234588-C)
005020086	Harada, T. (1968) Shinkunjozai "hosutokishin" (rinkasuiso) ni kansuru kenkyu (dai 6-ho): "hosutokishin" no hakka, bakuhatsu ni kansuru shiken. [Studies of the new fumigant "phostoxin" (hydrogen phosphide). VI: Ignition and explosion tests of "phostoxin".] Shokuryo Kenkyujo Kenkyu Hokoku. [Food Research Institue, Research Report.] (23):56-60.
000005907	Research Products Company (19??) General Specification of Detia Gas-EX-B. (Unpublished study received Aug 10, 1971 under 2548-EX-1; CDL:126817-A)
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000005746	Research Products Company (19??) Chemistry Data. (Unpublished study received Jan 6, 1977 under 2548-62; CDL:227594-A)
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005007617	Sonomura, H.; Miyauchi, T. (1969) Preparation of aluminum phosphide by solution-growth method. Japanese Journal of Applied Physics 8(10):1263.
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MRID #	Citation
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Environmental Fate (Part V)

MRID #	Citation
000005735	Childs, D.P.; Overby, J.E.; Niffenegger, D. (19??) Phosphine fumigation of flue-cured tobacco warehouses for control of the cigarette beetle. Tobacco 168(21):20-25. (Also *In* unpublished submission received May 21, 1976 under 5857-5; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:230915-B)
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000005737	Edmond, D.E.; Hadden, R.; Yu, G. (1971) The penetration of phosphine gas into lined tobacco cases during atmospheric fumigation. Tobacco (Jul 23):103-106. (Also In unpublished submission received May 21, 1976 under 5857-5; submitted by Phostoxin Sales, Inc.; Alhambra, Calif.; CDL:230915-D)
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000005662	Lauhoff Grain Company (1966) Cooperative Experimental Fumigation of Rolling Boxcars Using Phostoxin, August, 1966. (Unpublished study received Oct 14, 1966 under unknown admin. no.; submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:104158-A)
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005016261	Ruschel, A.P.; Da Costa, W.F. (1966) Fixacao simbiotica de nitrogenio atmosferico em feijao (* *Phaseolus vulgaris* L.). III. Influencia de alguns inseticidas e fungicidas. [Symbiotic fixing of atmospheric nitrogen in the French bean (*Phaseolus vulgaris* L.). III. Effect of some insecticides and fungicides.] Pesquisa Agropecuaria Brasileira. [Brazilian Agricultural and Veterinary Research.] 1:147-149.

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MRID #	Citation
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MRID #	Citation
000026937	Hackenberg, U. (1969) Investigation Report: 2 Years Toxicity Studies with Phostoxin"(R) --Treated Food on Rats. (Unpublished study received Aug. 2, 1971 under 2F1184; prepared by Institut fuer Industrielle und Biologische Forschung, submitted by Phostoxin Sales, Inc., Alhambra, Calif.; CDL:221725-L)
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Residue Chemistry (Part VII)

MRID #	Citation
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005007190	Bruce, R.B.; Robbins, A.J.; Tuft, T.O. (1962) Phosphine residues from phostoxin-treated grain. Journal of Agricultural and Food Chemistry 10(1):18-21.
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